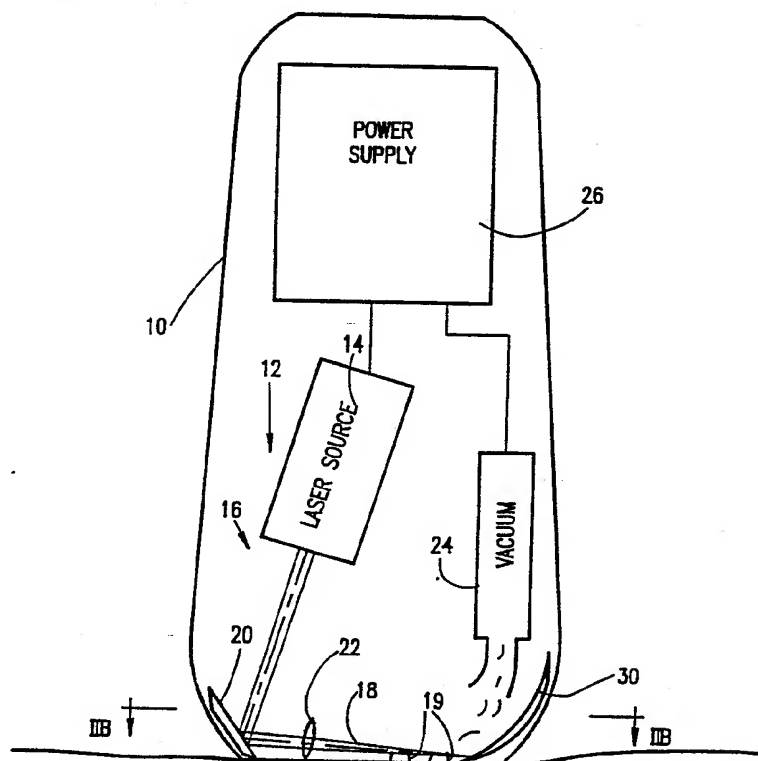




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : B26B 19/00, 21/00, B23K 26/00	A1	(11) International Publication Number: WO 92/16338 (43) International Publication Date: 1 October 1992 (01.10.92)
(21) International Application Number: PCT/GB92/00426 (22) International Filing Date: 10 March 1992 (10.03.92) (30) Priority data: 97531 12 March 1991 (12.03.91) IL (71)(72) Applicant and Inventor: KELMAN, Elliot [GB/GB]; 44 Western Avenue, London NW11 9PR (GB). (74) Agent: FREED, Arthur, Woolf; Reginald W. Barker & Co., 13 Charterhouse Square, London EC1M 6BA (GB). (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC (European patent), MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, RU, SD, SE, SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent), US.		Published <i>With international search report.</i>

(54) Title: HAIR CUTTING APPARATUS**(57) Abstract**

Hair cutting apparatus including a housing (10) and laser apparatus (12) disposed in the housing (10) and arranged to provide a beam of light (18) impinging on hair (19) to be cut, the beam of light (18) being operative to cut the hair (19).

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HAIR CUTTING APPARATUS

The present invention relates to hair cutting apparatus generally.

BACKGROUND OF THE INVENTION

There exists a great variety of hair cutting apparatus. These include single or multiple blade razors which are pulled across the surface of the skin and devices having an electrically powered vibratory element which drives opposing blades in a scissors type action.

U.S. Patent 3,934,115 describes a method and apparatus for electric singe cutting in which heated and opposed edges of two thin strips of metal form a slot, at which hair extending therethrough is singed to effect severance of the hair.

SUMMARY OF THE INVENTION

The present invention seeks to provide improved hair cutting apparatus.

There is thus provided in accordance with a preferred embodiment of the present invention hair cutting apparatus including a housing and laser apparatus disposed in the housing and arranged to provide a beam of light impinging on hair to be cut, the beam of light being operative to cut the hair.

In accordance with a preferred embodiment of the present invention, the laser apparatus is operative to provide a beam of light at a wavelength which is strongly absorbed by hair to be cut but not strongly absorbed by adjacent tissue.

In accordance with a preferred embodiment of the present invention, the wavelength of the beam is such that it is generally not absorbed by human skin.

A preferred wavelength range for operation of the shaving apparatus is 0.8 micron.

In accordance with a preferred embodiment of the invention the operational wavelength of the laser apparatus is selected to be such that only hairs of a certain color, such as white or gray hairs, are cut and the remainder of the hairs are not cut. A wavelength of 0.8 micron is suitable for this purpose. Such apparatus may be particularly useful for removing unwanted white or gray hairs automatically.

In accordance with a preferred embodiment of the present invention, the laser apparatus also comprises optical transfer means for directing the beam to the hair. The optical transfer means may include refraction and reflection means having

optical power.

Additionally in accordance with a preferred embodiment of the invention, hair collection apparatus may also be provided in the housing for collecting loose hairs that have been cut by the laser beam. The hair collection apparatus may comprise a vacuum device or alternatively or additionally, electrostatic hair collection apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Fig. 1A is a pictorial illustration of the use of a shaver constructed and operative in accordance with a preferred embodiment of the present invention;

Fig. 1B is a pictorial illustration of the use of a laser hair cutter constructed and operative in accordance with a preferred embodiment of the present invention;

Fig. 2A is a simplified sectional illustration of a laser shaver constructed and operative in accordance with a preferred embodiment of the present invention.

Fig. 2B is a simplified sectional illustration taken along the lines 2B - 2B of Fig. 2A;

Fig. 3A is a simplified sectional illustration of a laser shaver constructed and operative in accordance with another preferred embodiment of the present invention;

Fig. 3B is a simplified sectional illustration taken along the lines 3B - 3B of Fig. 3A; and

Fig. 4 is a simplified sectional illustration of a laser hair cutter constructed and operative in accordance with another preferred embodiment of the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Reference is now made to Figs. 1A, 2A and 2B which illustrate a laser shaver constructed and operative in accordance with a preferred embodiment of the present invention. The laser shaver preferably comprises a housing 10, typically formed of plastic or of any other suitable material. Disposed within housing 10 is laser apparatus 12, preferably comprising a laser source 14 and laser beam transfer optics 16, which direct a laser beam 18, produced by the laser source 14 to hairs 19 to be cut.

In accordance with a preferred embodiment of the present invention, the laser source 14 comprises a semiconductor laser such as a Gallium Arsenide laser, preferably operative to provide an output laser beam at a wavelength which is strongly absorbed by hair, such as facial hair but which is not strongly absorbed by surrounding tissue, such as skin. A preferred wavelength is 0.8 micron, although it is assumed that other wavelengths may also be suitable.

It is a particular feature of the present invention that suitable selection of the operative wavelength of the laser source 14 enables hair to be vaporized and carbonized at the location of impingement of the laser beam 18 thereon, thus separating that portion of the hair still attached to the hair follicle from that extending outward from the impingement location, thereby producing a hair cutting effect.

It is also a particular feature of the present invention that by suitable selection of the operative wavelength of the laser source only hair of a selectable color or range of colors may be cut, while hairs of other colors are left

intact. In such a way white or gray hair may be automatically removed by a simple combing action.

The laser beam transfer optics 16 preferably comprise reflective optics, such as a mirror 20 and refractive optics such as a lens 22. Any other suitable arrangement of laser beam transfer optics 16, including any suitable optical element or elements may alternatively be employed.

In accordance with one preferred embodiment of the present invention, there is also provided a laser beam absorber 30 for absorbing the laser beam and thus preventing spurious impingements thereof.

Reference is now made to Figs. 3A and 3B which illustrate a preferred embodiment of laser shaver in which the laser beam transfer optics is designed to provide multiple reflections of the laser beam over a shaving region. In this case, the absorber 30 is replaced by at least two mirrors 32 and preferably a generally rectangular circumferential mirror assembly which is operative to provide a back and forth pattern of laser beams, which can be effective for cutting hair over a relatively large area. It is appreciated that in this embodiment, initial impingement of the laser beam on mirror 20 is such as to produce a reflection which is not perpendicular to the planes of mirrors 32.

According to a preferred embodiment of the present invention, there is provided apparatus for collecting loose hairs, which are cut by the impingement thereon of laser beam 18. The apparatus for collecting loose hairs preferably comprises

electrically operated vacuum apparatus 24, such as a suction blower but may alternatively comprise any other suitable hair collection apparatus, such as electrostatic apparatus.

Both the laser source 12 and the vacuum apparatus may receive electrical power from a suitable power supply 26, which may be battery powered or alternatively powered by an external source of current.

Reference is now made to Fig. 4, which illustrates hair cutting apparatus constructed and operative in accordance with a preferred embodiment of the present invention and comprising many of the same elements as in the embodiment of Figs. 2A, 2B, 3A and 3B, which are indicated by identical reference numerals. In the embodiment of Fig. 4, there is provided a comb portion 40 which arranges the hairs 42 on a person's head, generally in a plane so that they can be impinged upon by a laser beam 18, which may be focussed thereon by a lens 22. Alternatively lens 22 may be eliminated. As a further alternative additional optical apparatus may be provided for positioning or configuring the laser beam, directing it along multiple paths or effecting scanning thereof.

It is a particular feature of the embodiment of Fig. 4, that color specific cutting may be provided, thus enabling white or gray hairs to be automatically cut, while leaving uncut dark colored hair. Additionally or alternatively, a hair thinning function may be provided, whereby only a desired percentage of all hairs may be cut by the laser beam.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the claims which follow:

C L A I M S

1. Hair cutting apparatus comprising a housing and laser means disposed in the housing and arranged to provide a beam of light impinging on hair to be cut, the beam of light being operative to cut the hair.

2. Hair cutting apparatus according to claim 1 and wherein said laser means is operative to provide a beam of light at a wavelength which is strongly absorbed by hair to be cut but not strongly absorbed by adjacent tissue.

3. Hair cutting apparatus according to claim 2 and wherein said wavelength of the beam is such that it is generally not absorbed by human skin.

4. Hair cutting apparatus according to any of the preceding claims and wherein said wavelength of the beam is such that it is generally absorbed by hair in a predetermined color range but is not generally absorbed by hair outside of said color range.

5. Hair cutting apparatus according to claim 4 and wherein said wavelength is such that it is generally absorbed by white and gray hair, producing cutting thereof but is not generally absorbed by hair of other colors.

6. Hair cutting apparatus according to any of claims 2 - 5 and wherein said wavelength is 0.8 micron.

7. Hair cutting apparatus according to any of claims 1 - 6 and wherein said laser means also comprises optical transfer means for directing the beam to the hair.

8. Hair cutting apparatus according to claim 7 and wherein said optical transfer means includes refraction and reflection means having optical power.

9. Hair cutting apparatus according to any of the preceding claims and also comprising hair collection means in the housing for collecting loose hairs that have been cut by the laser beam.

10. Hair cutting apparatus according to claim 9 and wherein said hair collection means comprises a vacuum device.

11. Hair cutting apparatus according to any of claims 7 - 10 and wherein said optical transfer means comprise means for producing multiple reflections of said laser beam.

12. Hair cutting apparatus according to any of claims 7 - 11 and wherein said optical transfer means comprise means for focusing said laser beam.

13. A method for color selectively cutting hair comprising the steps of:

providing a laser beam having a wavelength which is strongly absorbed by hair of a predetermined color range, which

hair it is sought to cut and which is not strongly absorbed by hair of a color outside of the predetermined color range, which it which is sought not to cut; and

causing the laser beam to impinge on hair for cutting those hairs of said predetermined color range while not cutting those hairs of a color outside of the predetermined color range.

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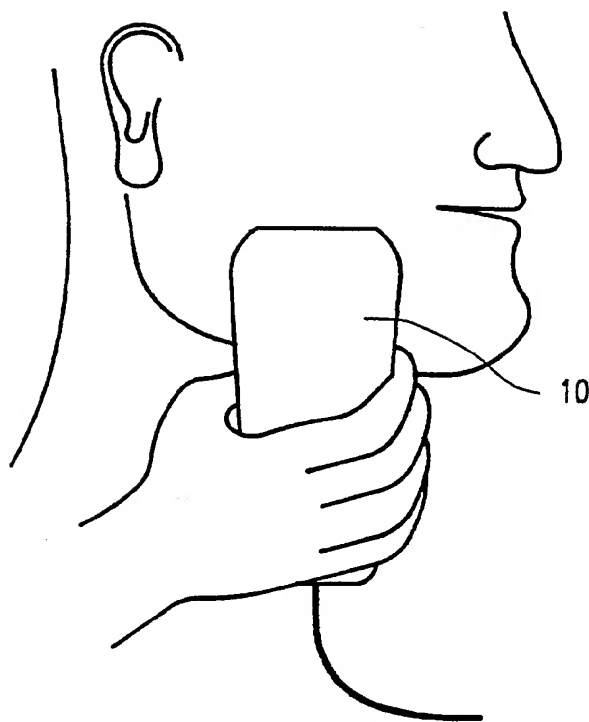


FIG.1A

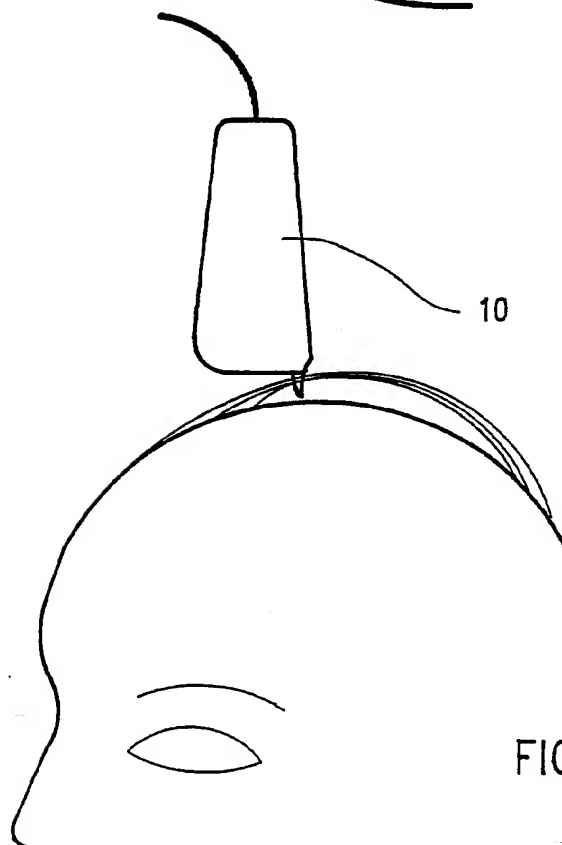


FIG.1B

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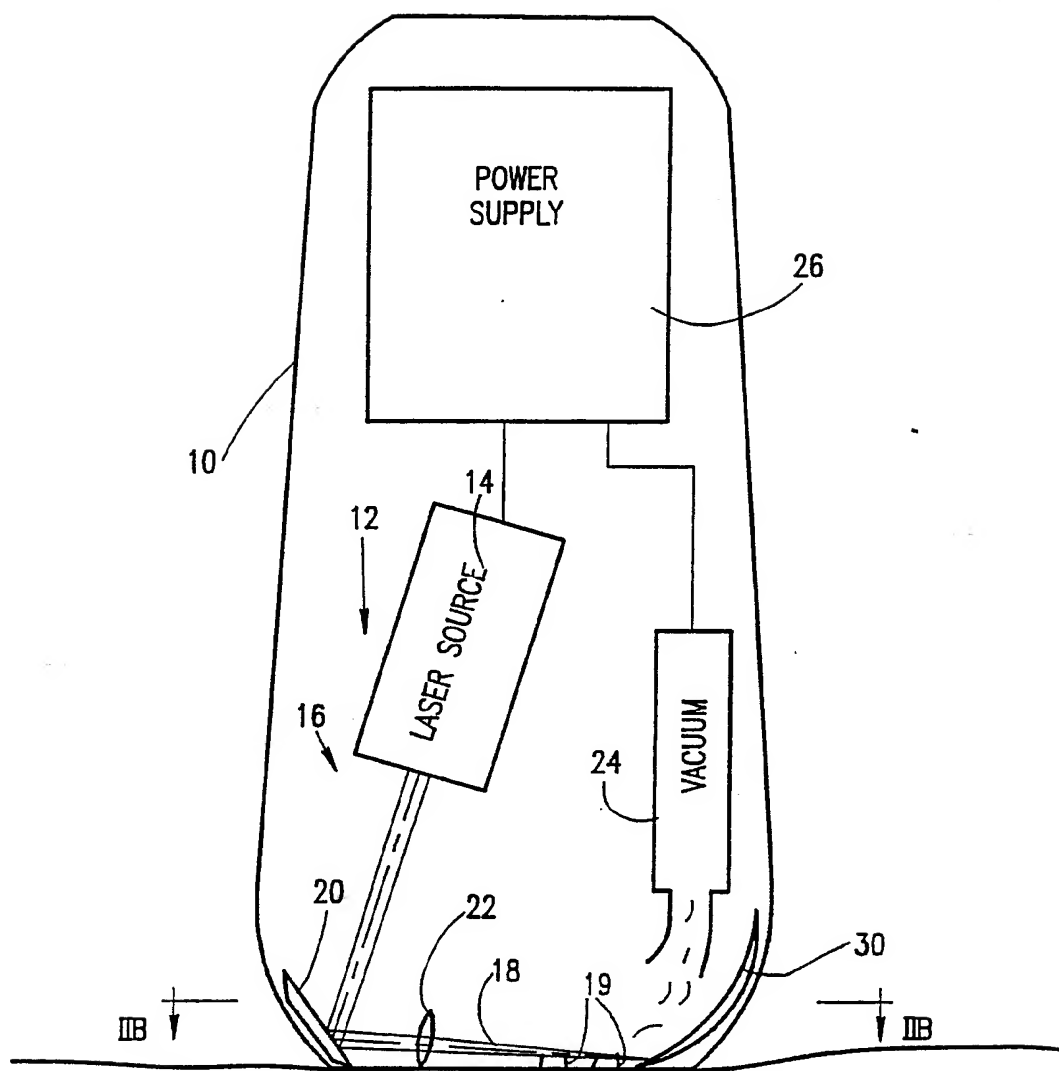
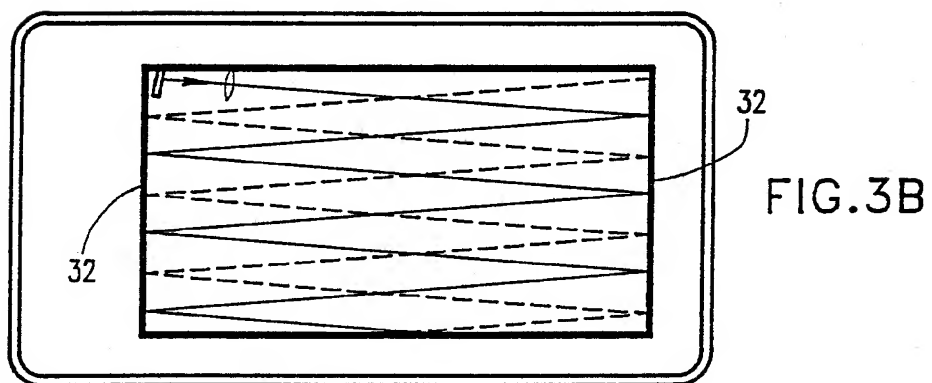
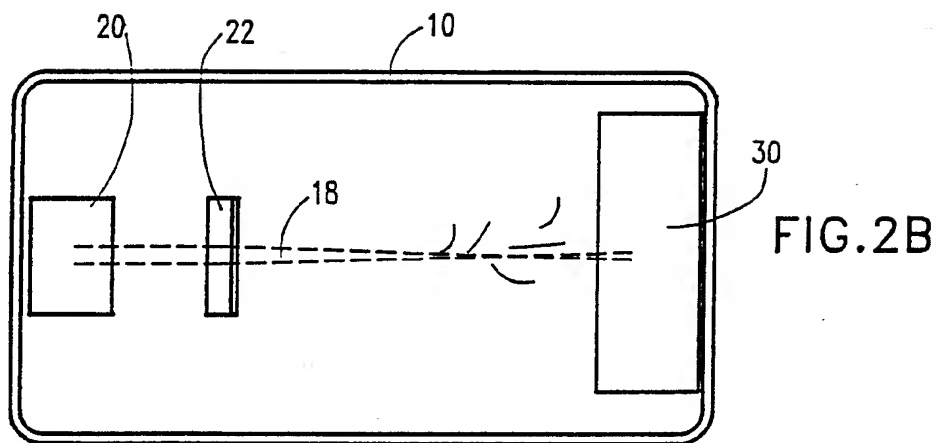


FIG.2A

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H/5

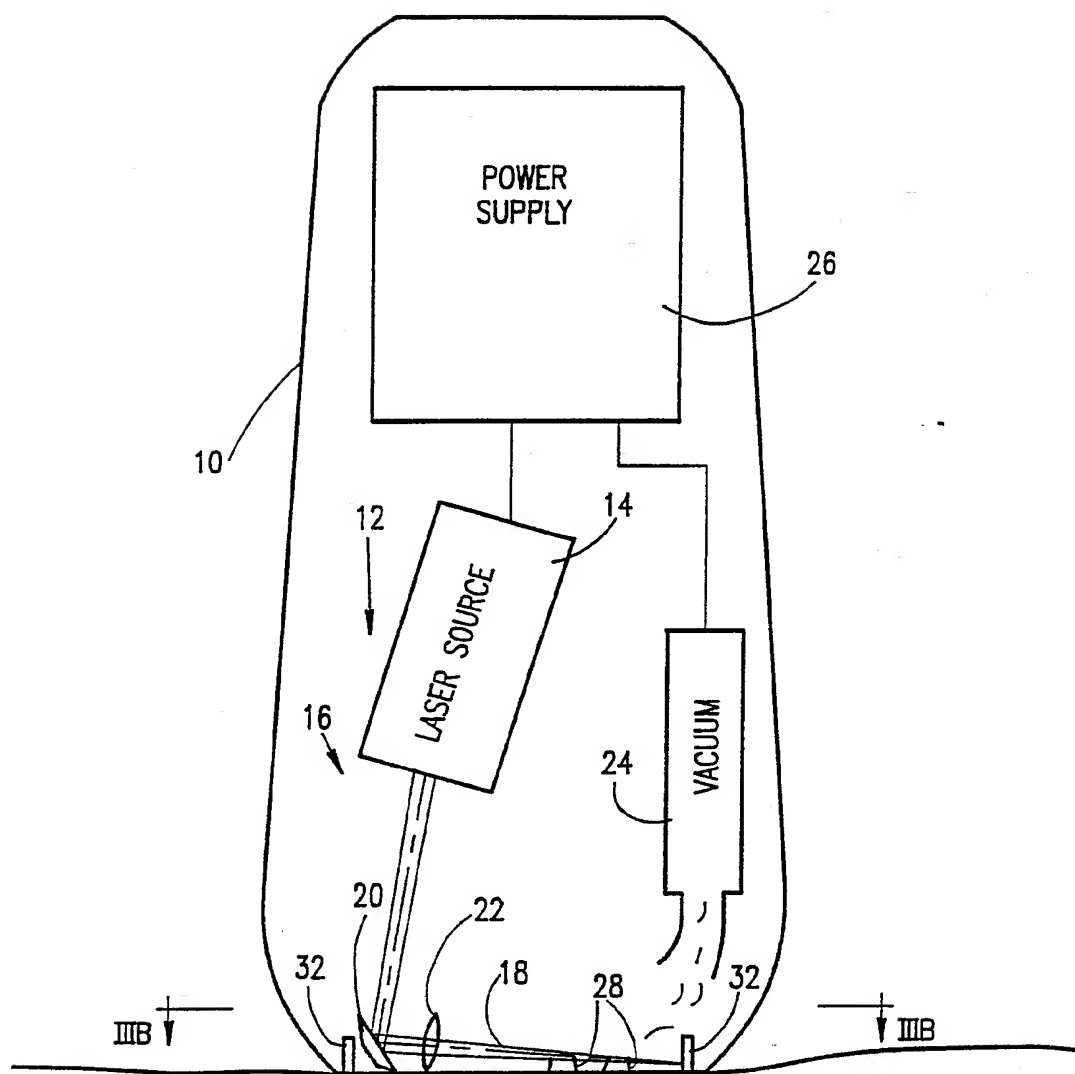


FIG.3A

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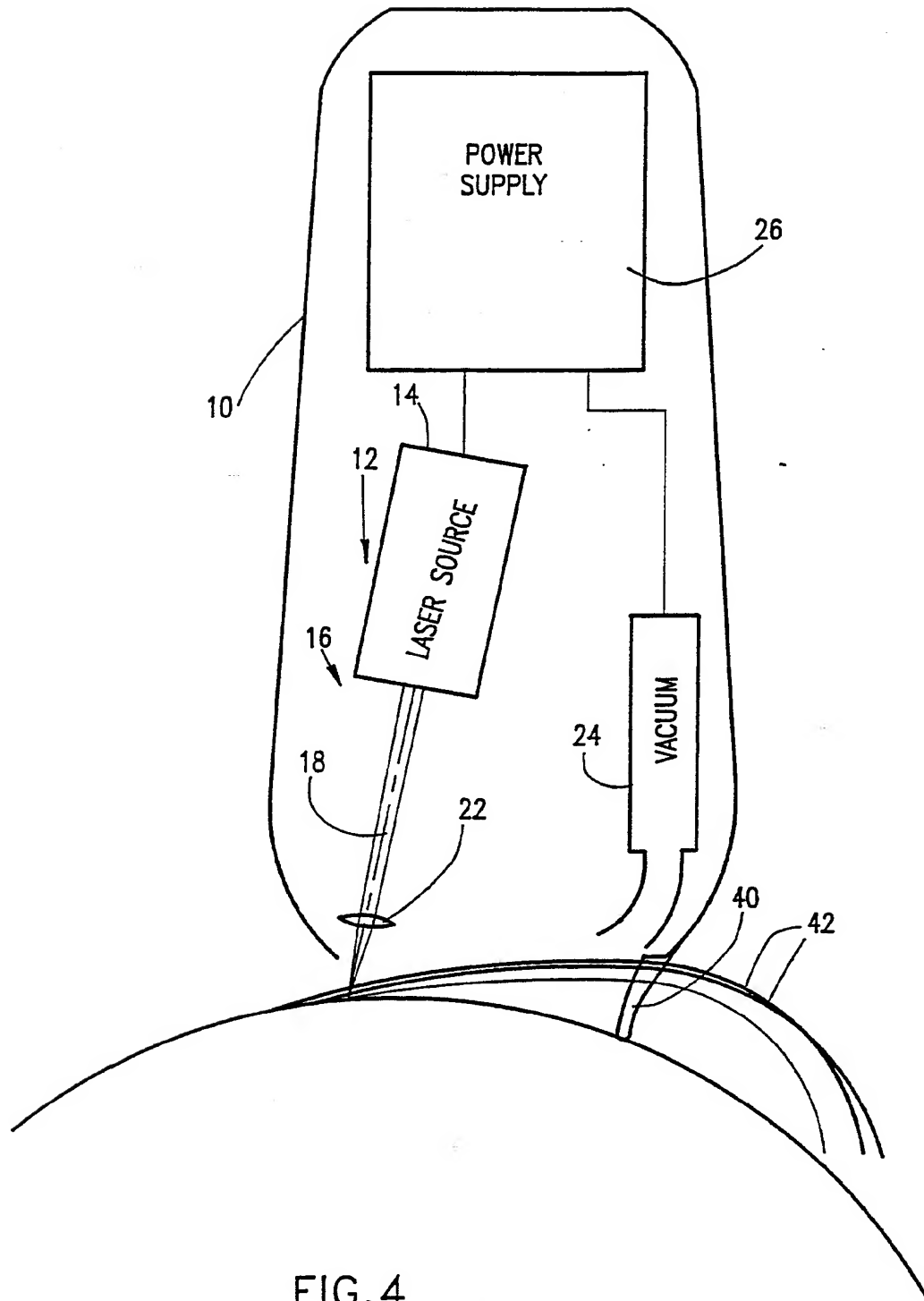
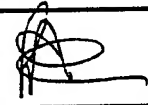


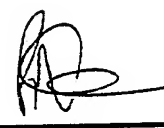
FIG.4

INTERNATIONAL SEARCH REPORT

PCT/GB 92/00426

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 B26B19/00; B26B21/00; B23K26/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	B26B ; B23K ; A61B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
P,X	WO,A,9 106 406 (SIMON) 16 May 1991	1-5,7,8, 12
P,Y	see page 3, line 36 - page 5; claims; figures	9,10
Y	--- US,A,4 578 558 (J. E. CLEGG) 25 March 1986 see figures 1-5,14 see column 1, line 39 - column 2, line 63 see column 4, line 30 - line 53	9,10
A	---	1,7,8,12
X	US,A,4 051 760 (M. GLENNAN) 4 October 1977 see figure 1 see column 2, line 30 - column 3, line 2 ---	1
	--- -/-	
<p>¹⁰ Special categories of cited documents : ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
10 JUNE 1992	30.06.92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	RAVEN P. 	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category ^a	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	<p>US,A,4 819 669 (E. POLITZER) 11 April 1989 see column 1, line 48 - column 2, line 41; figures 1,5 see column 3, line 34 - column 4, line 32 see column 5, line 24 - column 6</p> <p>---</p> 	1,7,11

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. GB 9200426
SA 57336**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9106406	16-05-91	DE-A- 3936367 EP-A- 0452459	08-05-91 23-10-91
US-A-4578558	25-03-86	None	
US-A-4051760	04-10-77	AU-A- 8246575 AU-A- 8246475	06-01-77 06-01-77
US-A-4819669	11-04-89	FR-A- 2579446 FR-A- 2583331 EP-A, B 0215878 WO-A- 8605676 JP-T- 62502724	03-10-86 19-12-86 01-04-87 09-10-86 22-10-87



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB92/00739 (22) International Filing Date: 22 April 1992 (22.04.92) (30) Priority data: 9108777.5 24 April 1991 (24.04.91) GB (71) Applicant (for all designated States except US): THE VICTORIA UNIVERSITY OF MANCHESTER [GB/GB]; Oxford Road, Manchester M13 9PL (GB). (72) Inventors; and (75) Inventors/Applicants (for US only) : KING, Terence, Alan [GB/GB]; 5 Lindsay Avenue, Cheadle Hulme, Stockport, Cheshire SK8 7BQ (GB). BANNISTER, John, Joseph [GB/GB]; 101 Shaw Lane, Glossop, Derbyshire SK13 9EE (GB).		(74) Agent: AJELLO, Michael, John; 207 Moss Lane, Bramhall, Stockport, Cheshire SK7 1BA (GB). (81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC (European patent), MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, RU, SD, SE, SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent), US. Published <i>With international search report.</i>
(54) Title: ERADICATION OF MARKS AND STAINS BY LASER (57) Abstract <p>A method of and apparatus is described for eradicating marks and stains at or beneath the surface of a substrate. The technique involves the use of a variable wavelength pulsed laser and an optical fibre delivery system to direct a spot of laser light at the treatment site. The laser produces an output in the form of a pulse having a duration in the range of 0.1 to 100 microseconds, at an energy level in the range of 0.5 to 5 Joules at a wavelength in the range of 400 to 900 nanometres. The output may consist of a single pulse or a sequence of pulses with a repetition rate selectable from 1 to 20 Hz. Marks in many different material may be eradicated using this technique. Examples are leather, wood, plastics and skin lesions such as tattoos and "port wine stains".</p>		

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ES	Spain				

ERADICATION OF MARKS AND STAINS BY LASER

THIS INVENTION concerns a method of and apparatus for eradicating marks and stains by laser and is particularly though not exclusively concerned with removal of pigmentation at or beneath the surface of a substrate.

Applications of the method are manifold, such as removal of marks and stains in hides or made up articles of leather, from wood especially in articles of furniture, from textiles and articles of clothing, and any application where pigmented or other marks or stains require elimination without damage to the surrounding substrate. A further example is the removal of skin lesions including pigmented lesions such as tattoo marks, moles, etc, and vascular lesions such as "port wine" stains.

Attempts have been made to remove pigmented marks using a Q-switched ruby laser. Such a laser generates a very short pulse duration in the region of 10 to 30 nano seconds and imposes power densities on the substrate in the region of 1,200 to 2,800 GW m^{-2} . Such power densities may cause damage to the surrounding substrate. Furthermore, a Q-switched ruby laser cannot deliver its treatment beam to the site using a flexible optical fibre. This is due to the very high power densities generated, and an articulated arm must be used for delivery.

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Additionally, ruby lasers operate on a single wavelength system, usually 693 nanometres.

An object of the present invention is to provide a method of and apparatus for the eradication of marks and stains, using a tunable laser which is effective in removal whilst operating at power densities far less than that generated by a Q-switched ruby laser, and with longer pulse duration, and wherein a flexible optical fibre may be used to deliver the treatment beam to the site.

According to the present invention there is provided a method of eradicating marks and stains at or beneath the surface of a substrate, comprising the step of directing at said surface, laser light generated by a variable wavelength pulsed laser, the laser operating to produce an output in the form of a pulse having a duration in the range of 0.1 to 100 microseconds, at an energy level in the range of 0.5 to 5 Joules, and at a wavelength in the range of 400 to 900 nanometres.

In a preferred method the laser produces a sequence of pulses with a repetition rate in the range of 1 to 20Hz.

Still further, the laser energy is preferably delivered to the surface via a single or multiple core optical fibre having a core size in the range of 600 to 1500 μ m.

In this way, the fibre optic delivery system may be hand-held allowing for the adjustment of the spot size of the laser beam

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on the surface, so that it can be selected within the range of 1 to 100mm in diameter.

The basic principle behind the method is that the laser is used to irradiate the site of the mark or stain in the substrate, and the wavelength at which the laser operates is chosen so that the mark or stain absorbs the radiation whilst unmarked surrounding substrate absorbs only little and so is not damaged. In this way a selective effect is obtained.

Further according to the present invention there is provided a pulsed laser apparatus for eradicating marks and stains at or beneath the surface of a substrate, the apparatus comprising a variable wavelength pulsed laser which is tunable to produce an output in the form of a pulse having a duration in the range of 0.1 to 100 microseconds, at an energy level in the range of 0.5 to 5 Joules, and at a wavelength in the range of 400 to 900 nanometres.

The apparatus comprises a fibre optic delivery system incorporating an optical fibre having a core size in the range 600 to 1500 μ m.

It is believed that the aforesaid method may be effected in many different applications such as the removal of pigmentation marks and stains at or beneath a translucent surface and also for creation of marks, for example, on self-coloured plastics material by removing pigmentation preferentially in selected areas thus to produce

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identification marks. One example of such application is an electrical cable having self-coloured sheathing which, by the application by the laser light in accordance with the invention may be selectively marked.

Coloured substrates may have a pattern or printing imposed thereon, by selective eradication of pigmentation. These effects may be established at and/or just beneath the surface of the substrate thus to be visible thereat.

An embodiment of the method in accordance with the invention will now be described in relation to the removal or reduction of skin lesions such as tattoo marks and port wine stains.

A tattoo mark is produced by a dark pigment (usually blue or black) introduced into the dermis. The particles of pigment are not removed by normal cellular activity and so the mark is permanent. The colour particles which make up the tattoo usually absorb well at wavelengths in the red part of the spectrum corresponding to a wavelength in the range of 650 to 700nanometres. However, these wavelengths are not absorbed by normal unmarked skin and so are scattered such that the energy is dissipated over a relatively large area with little or no effect on normal tissue.

In the lesion itself the radiation is very efficiently absorbed and so the energy is concentrated in or around the pigmented area.

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The design of the laser system is such as to increase the discrimination between tissue which forms part of the lesion, and normal unmarked tissue. For example, pulsed energy is important. A pulse of energy is deposited in the effected tissue for a time which is short when compared with the thermal relaxation time of the tissue. This means that the heat is generated locally and will not significantly spread by conduction to other, non-pigmented tissue. Thus, thermal injury to the adjacent tissue is avoided. This is an important aspect of the present invention for use on skin lesions, in contact with methods which use continuous wave lasers (including carbon dioxide and argon lasers) producing a much higher degree of thermal injury to the surrounding tissue. Furthermore, pulsed radiation generates an acoustic shock wave at the treatment site, which generally improves the effectiveness of the treatment. This appears to be due to the breakup of pigmented particles into smaller pieces which can then be removed by normal cellular activity. To generate a shock wave the pulse must be of a duration in the range of 0.1 to 100 microseconds, with an optimum duration of between 1 and 5 microseconds.

A tunable or variable wavelength laser may be used to treat skin lesions in several different ways. For example, for complete removal within one or two treatment sessions, the area treated should be in the region of 1 to 3mm in diameter, per pulse. However, the consequent high energy density results in selective thermal injury and there would be some scarring, but this will heal well and is not extensive. This process compares most favourably

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with existing practice using, for example, carbon dioxide lasers where there is no tissue selectivity and where removal of a large area of tissue is required with significant thermal injury and scarring. In effect, when laser apparatus is used in accordance with the invention it requires much less operator skill since it is less likely to produce accidental or co-lateral thermal damage when compared with existing processes.

In alternative eradication mode a spot size of 3 to 5mm may be treated requiring 3 to 4 sessions for each irradiated area. Consequently, this results in much less thermal damage but requires a greater number of process sessions.

Again, complete removal of pigmented lesions can be achieved with no residual scarring at all, but in this case some 5 to 7 process sessions on a larger site would be required, resulting in gradual fading of the lesion.

When the process is applied to the eradication of vascular lesions such as "port wine stains", the pulse duration must be selected in the range of 20 to 100 microseconds, whilst the wavelength should be in the region of 500 to 600 nanometres.

Selection of the operating parameters of the laser within the scope of the invention as aforesaid may be made according to the nature of the mark or stain to be removed, and of the substrate material.

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The laser may be either a flash tube excited laser or a tunable solid state laser such as a titanium sapphire laser.

It is envisaged that the operating ranges of the laser may be selected automatically by a control function which responds to a selection of a mark/substrate type. In this way, semi-skilled or perhaps even unskilled technicians may be capable of eradicating marks and stains effectively.

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CLAIMS

1. A method of eradicating marks and stains at or beneath the surface of the substrate, comprising the step of directing at said surface, laser light generated by a variable wavelength pulsed laser, the laser operating to produce an output in the form of a pulse having a duration in the range of 0.1 to 100 microseconds, at an energy level in the range of 0.5 to 5 Joules, and at a wavelength in the range of 400 to 900 nanometres.
2. A method according to Claim 1, wherein said pulse duration is in the range of 0.1 to 20 microseconds.
3. A method according to Claim 1, wherein said pulse duration is in the range of 20 to 100 microseconds.
4. A method according to Claim 1 or Claim 2, wherein said pulse wavelength is in the range of 400 to 800 nanometres.
5. A method according to Claim 1 or Claim 3, wherein said pulse wavelength is in the range of 500 to 600 nanometres.
6. A method according to any preceding claim, wherein the laser output consists of a sequence of pulses with a repetition rate selectable in the range of 1 to 20Hz.
7. A method according to any preceding claim, wherein the laser energy is delivered to the substrate surface via an optical fibre

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having a core size in the range of 600 to 1500 μ m.

8. Apparatus for eradicating marks and stains at or beneath the surface of a substrate, comprising a variable wavelength pulsed laser adapted to produce an output in the form of a pulse having a duration in the range of 0.1 to 100 microseconds, at an energy level in the range of 0.5 to 5 Joules, and at a wavelength in the range of 400 to 900 nanometres.

9. Apparatus according to Claim 8, wherein said pulse duration is in the range of 0.1 to 20 microseconds.

10. Apparatus according to Claim 8, wherein said laser is adapted to produce a pulse of duration in the range of 20 to 100 microseconds.

11. Apparatus according to Claim 8 or Claim 9, wherein said laser is adapted to produce a pulse of wavelength in the range of 400 to 800 nanometres.

12. Apparatus according to Claim 8 or Claim 10, wherein said laser is adapted to produce a pulse of wavelength in the range of 500 to 600 nanometres.

13. Apparatus according to Claim 8, in which said laser is adapted to produce a sequence of pulses at a repetition rate selectable from 1 to 20Hz.

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14. Apparatus according to any one of Claims 8 to 13, including an optical fibre connected to the output of the laser for delivery of said laser light, and having a core size in the range of 600 to 1500 μ m.

15. A method of eradicating skin lesions including pigmented lesions such as tattoo marks, moles, etc. and vascular lesions such as "port wine stains", the method comprising the steps of directing at the treatment site, laser light generated by a variable wavelength pulsed laser, the laser operating to produce an output in the form of a pulse having a duration in the range of 0.1 to 100 microseconds, at an energy level in the range of 0.5 to 5 Joules, and at a wavelength in the range of 400 to 900 nanometres.

16. A method according to Claim 15, wherein said pulse duration is in the range of 0.1 to 20 microseconds for removal of pigmented lesions.

17. A method according to Claim 15, wherein said pulse duration is in the range of 20 to 100 microseconds for removal of vascular lesions.

18. A method according to Claim 15 or Claim 16, wherein said pulse wavelength is in the range of 400 to 800 nanometres for pigmented lesions.

19. A method according to Claim 15 or Claim 17, wherein

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said pulse wavelength is in the range of 500 to 600 nanometres for vascular lesions.

20. A method according to Claim 15, wherein said pulse duration is in the range of 1 to 5 microseconds for pigmented lesions.

21. A method according to any one of Claims 15 to 20, wherein the laser energy is delivered to the lesion site via an optical fibre having a core size in the range of 600 to 1500 μm .

22. A method according to Claim 21, wherein the optical fibre delivery system is hand-held thus to allow adjustment of the spot size of the laser beam on the lesion site and thus in turn to determine intensity of the energy per pulse generated at the site.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 92/00739

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl.5 A 61 B 17/36 B 44 C 1/22		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl.5	A 61 B B 44 C	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	Conference on Lasers and Electro-Optics, Baltimore, Maryland, 21-24 May 1985, OSA/IEEE, M.S. SOBEY et al.: "Flashlamp-pumped dye-laser treatment of port wine stains", article WM46	1,2,4,5 7-9,11 12,14
Y	---	3,10
Y	US,A,4829262 (H. FURUMOTO) 9 May 1989, see column 1, line 1 - column 6, line 57	3,10
A	---	1,2,4-9 13,14
A	EP,A,0377050 (SUMITOMO ELECTRIC INDUSTRIES, LTD) 11 July 1990, see the whole document	1,7,8, 14
---	-/-	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁰ Special categories of cited documents :</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
30-06-1992	24. 07. 92	
International Searching Authority	Signature of Authorized Officer:	
EUROPEAN PATENT OFFICE	Maria Peis <i>Maria Peis</i>	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		Relevant to Claim No.
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	
A	EP,A,0172490 (MEDICAL LASER RESEARCH AND DEVELOPMENT CORP.) 26 February 1986, see page 1, line 1 - page 6, line 24; page 11, line 9 - page 16, line 3 ---	1-14
A	WO,A,9012545 (DERMALASE LTD) 1 November 1990, see page 2, line 10 - page 8, line 16 ---	1,6,13
A	Physics in Medicine and Biology, vol. 32, no. 12, December 1987, (Bristol, GB), A.R. HENDERSON et al.: "The 'light touch': a dermatology handpiece designed to improve the efficacy and safety of laser treatment of port-wine stains", pages 1627-1630 -----	1,7,8, 14

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB92/00739

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 15 - 22
because they relate to subject matter not required to be searched by this Authority, namely:
Please see Rule 39.1(iv) - PCT:
Method for treatment of the human or animal body by surgery or therapy,
as well als diagnostic methods.
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such
an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all
searchable claims.
2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of addiutonal search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9200739
SA 58731

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on 16/07/92
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4829262	09-05-89	US-A- 5066293	19-11-91
EP-A- 0377050	11-07-90	WO-A- 8912239	14-12-89
EP-A- 0172490	26-02-86	JP-A- 61058673	25-03-86
		US-A- 4733660	29-03-88
WO-A- 9012545	01-11-90	AU-A- 5422490	16-11-90

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(71) Applicant: WARNER-LAMBERT COMPANY [US/US];
201 Tabor Road, Morris Plains, NJ 07950 (US).
(72) Inventor: KOZILOWSKI, Stanislaw, D. ; 17 Platt Street,
Milford, CT 06460 (US).
(74) Agents: BULLITT, Richard, S. et al.; Warner-Lambert
Company, 201 Tabor Road, Morris Plains, NJ 07950
(US).

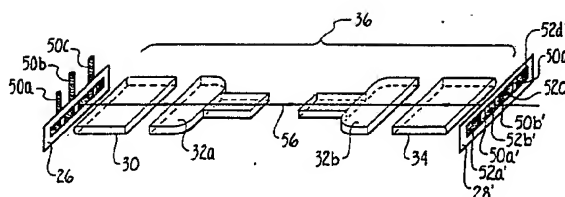
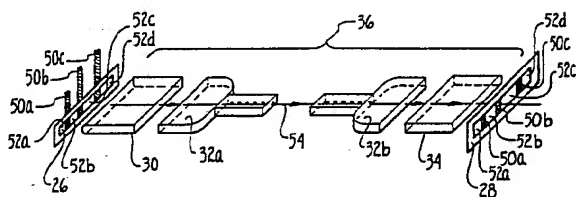
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(54) Title: HAIR ABLATION SYSTEM BY OPTICAL IRRADIATION



(57) Abstract

A shaving system which includes an apparatus for photoablating objects, such as hair, has an aperture (26) for framing the object (50) to be ablated. The shaving system also includes an optical system (36), a secondary light source (60) and a filter (28). In operation, whenever the secondary light source (60) is activated to illuminate the aperture (26) and object (50), the optical system (36) transfers light reflected from the object (50) and aperture (26) to the filter (28) which is located in the image plane of the optical system (36). In response to this reflected light, the filter (28) creates a negative of the object (50) and aperture (26). A laser source is then pulsed to radiate light through the negative filter (28), and onto the object, to photoablate the object.

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HAIR ABLATION SYSTEM BY OPTICAL IRRADIATION

FIELD OF THE INVENTION

The present invention pertains to shaving systems. More particularly, the present invention pertains to shaving systems which incorporate optical filters that selectively direct high intensity light into a field, but only onto the objects in the field which are to be photoablated. The present invention is particularly, but not exclusively, useful for shaving hair from the body surface of a person.

10

BACKGROUND OF THE INVENTION

Shaving hair from the body has been practiced by men and women since near the beginning of recorded time. Indeed, in many respects the instruments which are used today for this purpose still bear some rudimentary resemblance to the earlier shaving instruments. Specifically, both ancient shaving devices and modern day shaving devices have somehow generally included a sharpened edge, or blade, which is used to cut the hair close to the surface of the skin to give the person a shaven appearance. Over the years, improvements in shaving devices have been mostly the result of learning new and better ways to use more durable materials in the manufacture of longer lasting and sharper blades for the devices. Modern technology, however, has taken us to the point where we are now looking for alternative ways to more efficiently and conveniently shave ourselves. Such attempts, as is the case with the present invention, have focused on ways of severing hair from the body which are quite different from merely cutting the hair with a blade.

It is well known that many materials can be altered by a process which is generally referred to as photoablation. For photoablation, photons from a high intensity light source, such as a laser, are focused onto a material to alter the material in a way which causes it to be cut or severed. This result may, of course, be beneficial for

diverse applications and the intent here is not to limit the present invention to a single such application. Instead, the present invention pertains to all applications where it is necessary and essential to carefully control the photoablation process. One specific instance involves applications where human tissue is to be cut or severed.

It happens that photoablation is quite effective as a procedure for altering human tissue. As implied above, however, where human tissue is involved it is essential to effectively control the photoablation process. In essence this means that the light used for photoablation needs to be carefully and accurately focused onto only the specific area or part of the material or tissue which is to be cut or severed. The present invention recognizes this can be accomplished by properly filtering the light which is used to photoablate the material.

Accordingly, it is an object of the present invention to provide a device for photoablating objects, such as human hair, which focuses sufficient light energy onto the object to cut or sever the object. Another object of the present invention is to provide a device for photoablating objects which selectively focuses high intensity light only onto objects which are framed within a field. Still another object of the present invention is to provide a device for photoablating objects which filters or blocks unwanted energy from a high intensity light source to selectively direct light onto objects which are to be altered by photoablation. Yet another object of the present invention is to provide a device for photoablating objects which is easy to use, relatively simple to manufacture and comparatively cost effective.

SUMMARY OF THE INVENTION

In accordance with the present invention, a shaving device for photoablating hair includes a source of high intensity light, such as a laser, which is operationally

connected to the optical system of the device. This optical system includes an aperture, a filter device and an optical system. All of which may be mounted together in a housing.

5 When properly mounted, the optical system of the present invention is positioned between the aperture and the filter. More specifically, in relation to the optics established by the optical system, the aperture is located in the object plane, and the filter is located in the image
10 plane. Consequently, when objects, such as strands of hair, are framed in the aperture, the picture composed by the object in the aperture is transferred through the optical system and onto the filter in the image plane.

The device of the present invention also includes a
15 secondary light source which is positioned to illuminate objects as they are framed by the aperture and the filter. The picture which results from this illumination by the secondary light source is then transferred through the optical system as mentioned above, to the filter where a
20 negative of the picture is created to effectively establish a negative filter. High intensity light, e.g. a laser light, is then directed from the high intensity light source, through the negative filter and onto the objects framed by the aperture.

25 In one embodiment of the present invention the filter device is an element having an image recording medium which, in response to light from the secondary source that is reflected by the object, establishes a negative of the picture. This embodiment can include a tertiary light
30 source which radiates light at a wavelength that will erase the negative from the image recording medium of the filter. Alternatively, instead of a tertiary light source, a voltage source can be included which will erase the negative from the image recording medium at intervals as
35 the picture changes. For another embodiment of the present invention, the filter device incorporates an image

processor which receives light from the secondary source that is reflected by the object to generate a signal which is representative of a negative picture. This signal is then used to impact the high intensity light source. In
5 turn, the high intensity light source is programmed to accurately and selectively direct a beam of high intensity light onto only the objects that are to be photoablated.

In the operation of the particular embodiment for the present invention which uses an image recording medium as
10 the filter, the secondary light source is first activated to create the negative at the filter, the high intensity light source is then activated to use the negative filter for directing light onto the object to be ablated, and the negative is then erased. This sequence can be repeated as
15 necessary. In the operation of the embodiment of the present invention which uses an image processor as a filter, the secondary light source and the high intensity light source are alternately activated, as necessary.

For the particular application where the device of the
20 present invention is to be used as a shaving system, the aperture can be mounted in a housing and the housing can be attached to a handle which can be used to move the aperture across the surface to be shaved. The optical system and the negative filter can also be mounted in the housing or,
25 through the use of a suitable optical fiber system, can be mounted as a remote unit. Similarly, the various light sources can be remotely mounted as desired.

The novel features of this invention, as well as the invention itself, both as to its structure and its
30 operation will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, in which similar reference characters refer to similar parts, and in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a perspective view of the device of the present invention being used in an intended environment with a remote unit;

5 Figure 1B is a perspective view of an alternate embodiment of the device of the present invention in a cordless configuration without a remote unit;

Figure 2 is a perspective view of the device;

Figure 3 is a cross sectional view of the housing of
10 the device as seen along the line 3-3 in Figure 2;

Figure 4 is a perspective view of an optical system for focusing light;

Figure 5 is a perspective view of the optical system of the present invention forming a positive photographic
15 image;

Figure 6 is a perspective view of the optical system of the present invention with the negative filter established for operational use with a high intensity light source;

20 Figure 7 is a schematic diagram of the operative components of the present invention for an embodiment which incorporates a voltage source to erase an image recording medium;

Figure 8 is a schematic diagram of the operative
25 components of the present invention for another embodiment which incorporates a tertiary light source to erase an image recording medium; and

Figure 9 is a schematic diagram of the operative components of the present invention for still another
30 embodiment which incorporates an image processor.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to Figure 1A, a device for photoablating an object is shown in an intended environment and is generally designated 10. As shown in Figure 1A, the

device 10 is being used to shave facial hair. This application, however, is not limiting.

In Figure 1A, the device 10 is shown to include a razor 12 which is operatively connected by a cable 14 to a remote unit 16. Further, it can be seen that the remote unit 16 is formed with a cradle 18 which is formed to receive and hold the razor 12 when the razor 12 is not in use. With this device 10, a user 20 can remove the razor 12 from the cradle 18 of remote unit 16, and activate the unit 16 to shave hair from a body surface. In an alternate preferred embodiment of the present invention, as shown in figure 1B, the device 10 is shown in a cordless configuration. In this alternate embodiment, the cable 14 and remote unit 16 are eliminated and instead, all operative components of the device 10 are housed in the razor 12.

A more detailed view of the razor 12 of device 10 is presented in Figures 2 and 3. In Figure 2, specifically, it is shown that the razor 12 comprises a housing 22 and a handle 24 which is integrally attached to the housing 22. Although housing 22 is integral with the handle 24 for the embodiment shown in Figures 1-3, it will be appreciated that several forms of attachment between the housing 22 and the handle 24 can be established for the purposes of the present invention. Further, in Figures 1 and 2 the cable 14 is shown to extend from the handle 24. Again, there can be several ways in which razor 12 is connected with the remote unit 16. Importantly, Figures 2 and 3 also show that the housing 22 is formed with an aperture 26 that is both long and narrow. Stated differently, the aperture 26 is formed as a slit which has great width and very little height.

The relationship between the housing 22 of razor 12 and the operative optical elements of the device 10 are, perhaps, best shown in Figure 3. There it will be seen that the housing 22 is formed with an aperture 26 at its

front, and that a negative filter element 28 is positioned near the rear of the housing 22. As indicated in Figure 3, a series of lenses are positioned in the housing 22 for the purpose of transferring light between the aperture 26 and the negative filter 28. Specifically, this series of lenses includes, in sequence from the aperture 26 to the negative filter 28, a cylindrical lens 30, a relay lens 32 and a cylindrical lens 34. Together, the lenses 30, 32 and 34 comprise the optical system 36 of the device 10. A preferred configuration for this optical system 36 for the device 10 is best seen in Figures 5 and 6. When considering this configuration, it is to be appreciated that the relay lenses 32 can be positioned in any convenient arrangement which will effectively transfer light between the cylindrical lenses 30 and 34. For example, instead of positioning the negative filter 28 in the housing 22 of razor 12, it is conceivable that the negative filter 28 be positioned in the remote unit 16 of the device 10. The determining element in each case will be the configuration and composition of the relay lens 32. Regardless of the particular configuration for the relay lens 32, it is important for the operation of the device 10 that the optical system 36 be configured so that its object plane is coincident with the aperture 26 and its image plane is coincident with the negative filter 28.

Figure 4 illustrates a typical lens configuration whereby high intensity light, such as a laser, can be focused for the purpose of photoablating an object. For this illustrated configuration the light is shown linearly focused. Specifically, a beam of high intensity light 38 is first directed through a converging cylindrical lens 40. The converging cylindrical lens 40 then confines the beam 38 onto a transfer element 42. As is well known in the art, this transfer element 42 can be any suitable structure, such as an optical fiber system, which is capable of effectively transferring light from one point to

another. For the typical lens configuration being discussed, a dispersion lens 44 is shown to spread the light in beam 38 from the dispersion lens 44 and onto an elongated cylindrical lens 46. The cylindrical lens 46 then linearly focuses the light to establish a cutting edge 48. For such a configuration, it is possible to focus the high intensity light beam 38 such that the established cutting edge 48 is only approximately one to two microns in thickness (1-2 microns), and has a depth of focus which is less than approximately one half millimeter (0.5 mm). For the purposes of the present invention, the optical system 36 incorporates similar optics.

Importantly for the present invention, depending on the direction in which light traverses the optical system 36, the system 36 linearly focuses light on either the object plane at the aperture 26, or on the image plane at the negative filter 28. In order to do this, the cylindrical lenses 30 and 34 are located at the opposite ends of the optical system 36, as shown in Figures 5 and 6. As indicated above, the relay lenses 32a,b can be of any type well known in the art.

With a configuration as shown for the optical system 36 in the Figures 5 and 6, whenever aperture 26 is positioned against objects 50 a,b and c (for example, hair) the objects 50 a,b and c are framed by the aperture 26. This framing creates a picture which includes the objects 50 a,b and c, as well as the spaces 52 a,b,c and d that appear around the objects 50. This picture is then transferred through optical system 36 by light 54 to be recomposed on the image plane of optical system 36 at negative filter 28. As will be appreciated by the skilled artisan, a negative of the picture, as framed at the aperture 26, will invert the dark and the light portions of the picture to make the picture appear as shown at the negative filter 28' in Figure 6. More specifically, objects 50 a,b and c which appear dark in aperture 26 will

appear as light objects 50 a',b' and c' at the negative filter 28'. Conversely, the light spaces 52 a,b,c and d which appear at aperture 26 will appear as dark spaces 52 a',b',c'and d' at the negative filter 28'. The
5 transformation of negative filter 28 into a negative of the picture of the objects 50 a,b and c framed by aperture 26 can be accomplished by components known in the art, in a manner to be subsequently discussed. Suffice for the moment that the negative filter 28' can be created by the
10 light 54 reflected from aperture 26 through the optical system 36.

Once the negative filter 28' has been established in response to the reflected light 54, high intensity light 56 can be directed through the filter 28' and focused by the
15 cylindrical lens 30 of optical system 36 onto the objects 50 a,b and c. Importantly, due to the filtering effect which the negative filter 28' has on light 56, the light 56 will be blocked from passing through the spaces 52 a,b,c and d at aperture 26 and will be focused on only the
20 objects 50 a,b and c. Consequently, when light 56 is focused in a manner as discussed above with reference to Figure 4, and depending on the wavelength of the light 56 and its ability to interact with the material of which the objects 50 a,b and c are composed, the objects 50 a,b and
25 c will be photoablated.

Several structural embodiments for establishing the negative filter 28' and for directing high intensity light 56 onto the objects 50 a,b and c to be photoablated are contemplated for the device 10. For example, Figure 7
30 shows the schematic of an embodiment for device 10 wherein the filter 28 includes an image recording medium that is responsive to light 54 to create the negative filter 28'. Several media, such as a liquid crystal or solid crystal display of any type well known in the pertinent art, can be
35 used for this purpose. Indeed, any reversible and erasable crystalline recording medium can be used for this purpose.

For the particular embodiment shown in Figure 7 a high intensity light source 58 is provided as well as a secondary light source 60 and a voltage source 62. Also included is a beam splitter 64 which, as shown in Figure 7, can be incorporated into the structure of the optical system 36 in a manner well known in the pertinent art.

In the operation of the structural embodiment shown in Figure 7, light from the secondary light source 60, is directed along a light path 66 toward the beam splitter 64 where it is directed onto the optical axis 68 of the optical system 36 and toward the aperture 26. This light is then reflected from objects 50 a,b,c and aperture 26 as the light beam 54. For purposes to be subsequently discussed, the beam of light 54 has a wavelength that is different from that of the high intensity light 56. Furthermore, the wavelength of the light 54 must be properly selected to be capable of creating a negative at the filter 28'.

After filter 28' has been established by the light beam 54 which originated at secondary light source 60, the high intensity light source 58 is activated. With the activation of high intensity light source 58, high intensity light 56 is directed along a beam path 70 and through negative filter 28'. After being filtered at the negative filter 28' the high intensity light is passed along the optical axis 68 of optical system 36 to be focused through aperture 26 and into the cutting edge 48. With aperture 26 adjacent the objects 50, only those parts of cutting edge 48 are activated with focused high intensity light that coincides with the objects 50 a, b and c. The objects 50 are thus photoablated.

As shown in Figure 7, the voltage source 62 is connected via electrical conductor 72 with the negative filter 28. For this embodiment of the device 10, the voltage source 62 is appropriately activated to erase the negative filter 28' after secondary light source 60 is

activated to establish the filter 28' and after high intensity light source 58 has used the negative filter 28' to direct high intensity light 56 onto only the objects 50. With the erasure of filter 28' the voltage source 62
5 prepares filter 28 for the creation of a new negative filter 28'. The new negative filter 28' will, of course, be characteristic of the new picture presented as aperture 26 is placed adjacent new objects 50. As indicated, secondary light source 60, high intensity light source 58
10 and voltage source 62 are each activated in the ordered sequence described above to photoablate the objects 50. The sequence can be repeated as necessary, and the time interval in each cycle during which high intensity light source 58 is activated is preferably less than ten
15 milliseconds (10 msec).

For the embodiment of device 10 shown in Figure 7, both beam path 66 and beam path 70 can be made of an optical fiber system of any type well known in the pertinent art. Consequently, beam paths 66 and 70 can be
20 combined with the electrical connector 72 as components of the cable 14 which connects remote unit 16 with razor 12. In this configuration, the high intensity light source 58, the secondary light source 60 and the voltage source 62 can be mounted in the remote unit 16. Of course, for the
25 alternate embodiment of device 10 shown in Figure 1B, the same optical fiber system can be used with the high intensity light source 58, the secondary light source 60 and the voltage source 62 mounted on razor 12. This embodiment thus eliminates the need for cable 14 and remote
30 unit 16. Indeed, as indicated above, the operative elements in each of the various embodiments for the device 10 can be mounted on razor 12.

In another embodiment of the present invention, as shown in Figure 8, a combined light source 74 is used which
35 includes the high intensity light source 58 in combination with a tertiary light source. Again, an image recording

medium, such as the filter 28 is used. Also, the secondary light source 60 is still included, and it performs substantially the same function in substantially the same way as disclosed for the secondary light source 60 in Figure 7. The voltage source 62, however, is eliminated. Instead, the tertiary light source of combined light source 74 is used to erase the negative 28' to prepare filter 28 for the creation of a new negative filter 28'. Necessarily, the wavelength of light from the tertiary source must be different from the wavelengths of the light from both the secondary source 60 and the high intensity light source 58. Furthermore, while light from secondary source 60 must be capable of converting filter 28 into filter 28', light from the tertiary source must be capable of erasing the filter 28' and converting it back into the filter 28.

In the operation of the embodiment for device 10 as shown in Figure 8, the secondary light source 60 is activated to direct light 54 along the optical axis 68 to establish negative filter 28'. High intensity light source 58 is then activated to direct the light beam 56 through the negative filter 28' and along optical axis 68 to be focused through aperture 26 onto cutting edge 48. Thus, only beams of light 56 which have passed through negative filter 28', and which therefore correspond with objects 50, will be focused onto cutting edge 48 to photoablate the objects 50. The tertiary light source is then activated to erase the filter 28' and the sequence is repeated as necessary. Preferably, the time interval during which high intensity light source 58 is activated during any one cycle of the sequence will be less than ten milliseconds (10 msec). Additionally, as will be appreciated by the skilled artisan, the high intensity light source 58 and the tertiary light source can be separated, rather than being integrated into the combined light source 74.

Figure 9 shows yet another embodiment of the device 10 wherein the filter 28 comprises an image processor, such as a charge couple device well known in the pertinent art. For this embodiment, a microprocessor 76 is electrically
5 connected to both the image processor of filter 28 via an electrical connection 78 and to a combined light source 80. In this instance, the combined light source 80 includes both the high intensity light source 58 and the secondary light source 60. Light from the combined light source 80
10 is directed onto the optical axis 68 of optical system 36 via optical path 82 and a beam splitter 84.

In the operation of the embodiment shown in Figure 9, the combined light source 80 is energized to first activate the secondary light source 60. As disclosed above, light
15 54 from the secondary light source 60 establishes the negative filter 28'. The image processor of filter 28 then creates electrical signals that are representative of the negative filter 28' which corresponds to a picture of objects 50 framed by the aperture 26. Next, these signals
20 are processed by the microprocessor 76 which, in turn, activates the high intensity light source 58. The resultant beam of high intensity light 56 from the combined light source 80 is configured to correspond with negative filter 28' and is passed through the optical system 36 to
25 be focused onto cutting edge 48. Consequently, because the light 56 is configured to correspond with negative filter 28', the light 56 is focused on cutting edger 48 only where there are objects 50

In the operation of the embodiment shown in Figure 9,
30 the high intensity light source 58 and the secondary light source of combined light source 80 are alternately activated by the microprocessor 76. Specifically, after secondary light source 60 has been activated to create the negative filter 28', the high intensity light source 58 is
35 activated to generate a light beam 56 which corresponds with the negative filter 28'. With the light beam 56 the

objects 50 are photoablated. As implied, this sequence can be repeated as necessary or desired. Preferably, the time interval in each sequence during which high intensity light source 58 is activated is, as with the other
5 embodiments disclosed above, less than ten milliseconds in duration (10 msec). Further, it will be appreciated by the skilled artisan that high intensity light source 58 and secondary light source 60 need not be combined into combined light source 80 but can, instead, be separated as
10 desired.

While the particular device for photoablating objects as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely
15 illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of the construction or design herein shown other than as defined in the appended claims.

I claim:

1. A device for photoablating an object which
3 comprises:
a high intensity light source (58);
means for framing said object (26);
6 means for creating a negative of said framed
object (28);
means for using said negative to filter light
9 from said high intensity light source; and
means for directing said filtered light onto said
object to photoablate said object (36).

2. A device as recited in claim 1 further comprising
an optical system (36) positioned between said framed
3 object (50) and said means for creating a negative (28) to
present an image of said framed object at said means for
creating a negative.

3. A device as recited in claim 2 wherein said negative creating means comprises:

3 a secondary light source (60) for radiating light
at a selected wavelength, said selected wavelength
being different from the wavelengths of said high
6 intensity light;

an image recording medium (28) responsive to
light of said selected wavelength, radiated from said
9 secondary source and reflected from said framed object
(50) through said optical system (36), to create said
negative according to said image; and

12 means for erasing said negative (62) from said
image recording medium.

4. A device as recited in claim 3 wherein said image recording medium is a liquid crystal element.

5. A device as recited in claim 3 wherein said means for erasing said negative is a voltage source electrically
3 connected with said image recording medium.

6. A device as recited in claim 3 wherein said means for erasing said negative is a tertiary light source for
3 irradiating said negative with light of suitable wavelength and intensity to erase said negative.

7. A device as recited in claim 3 further comprising means (76) for selectively activating said high intensity
3 light source during a time interval when said image recording medium establishes said negative.

8. A device as recited in claim 7 wherein said time interval is less than approximately ten milliseconds (10
3 msec).

9. A device as recited in claim 2 wherein said negative creating means comprises:

3 a secondary light source (60) for radiating light
at a selected wavelength, said selected wavelength
being different from the wavelengths of said high
6 intensity light;

an image processor (76) responsive to light of
said selected wavelength, radiated from said secondary
9 source and reflected from said framed object through
said optical system (36), to create a signal
representative of said negative according to said
12 image; and

means for activating said high intensity source,
said activating means being connected between said
15 image processor and said high intensity light source,
to radiate high intensity light from said high
intensity light source according to said signal.

10. A device as recited in claim 9 wherein said high
intensity light source is pulse activated to sequentially
3 radiate high intensity light during predetermined time
intervals.

11. A device as recited in claim 2 further comprising
a housing (22); a handle (24) attached to said housing (22)
3 for manipulating said housing; and wherein said framing
means is an aperture (26) mounted on said housing.

12. A device as recited in claim 11 wherein said
optical system includes an optical fiber system to
3 optically couple said aperture with said negative creating
means.

13. A device as recited in claim 12 wherein said
object is body hair.

14. A device as recited in claim 1 wherein said high intensity light source is a source of laser light.

15. A device for photoablating an object (50) which comprises:

3 a high intensity light source (58);
 an aperture (26) positionable against said object
to establish a picture of said aperture and said
6 object;
 a filter (28), with means for establishing said
filter as a substantial equivalent to a negative of
9 said picture; and
 means (36) for directing light from said high
intensity light source, and through said filter, onto
12 said object to photoablate said object.

16. A device as recited in claim 15 wherein said directing means includes an optical system positioned
3 between said object and said filter to present an image of said picture at said filter.

17. A device as recited in claim 16 wherein said means for establishing said filter as a negative of said
3 picture comprises a secondary light source (60) for radiating light at a selected wavelength, said selected wavelength being different from the wavelength of said
6 laser light; and wherein said filter (28) includes is an image recording medium responsive to light of said selected wavelength to create said negative according to said
9 picture.

18. A device as recited in claim 17 further comprising a voltage source (62) and wherein said filter
3 (28) is connected to said voltage source (62) to selectively erase said negative from said image recording medium.

19. A device as recited in claim 17 further comprising a tertiary light source (80) and wherein said
3 tertiary light source is positioned for irradiating said negative with light of suitable wavelength and intensity to erase said negative from said image recording medium.

20. A device as recited in claim 17 wherein said image recording medium is a liquid crystal element and said
3 device further comprises means for selectively activating said laser source during a time interval less than approximately ten milliseconds (10 msec) while said liquid
6 crystal element creates said negative.

21. A device as recited in claim 17 wherein said image recording medium is a reversible and erasable
3 crystalline recording medium and said device further comprises means for selectively activating said laser source during a time interval less than approximately ten
6 milliseconds (10 msec) while said liquid crystal element creates said negative.

22. A device as recited in claim 16 wherein said means for establishing said filter as a negative of said picture comprises:

a secondary light source (60) for radiating light at a selected wavelength, said selected wavelength being different from the wavelength of said high intensity light;

an image processor (76) responsive to light of said selected wavelength, radiated from said secondary source and reflected as said picture through said optical system, to create a signal representative of said picture; and

means for activating said high intensity light source, said activating means being connected between said image processor and said high intensity light source, to radiate high intensity light from said high intensity light source according to said signal.

23. A device as recited in claim 22 wherein said high intensity light source is a laser source and is pulse activated to sequentially radiate laser light during predetermined time intervals.

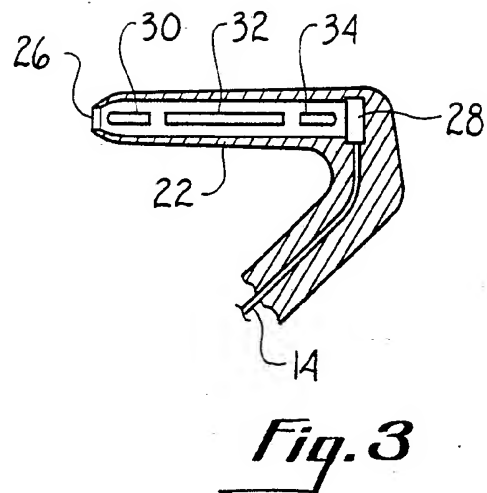
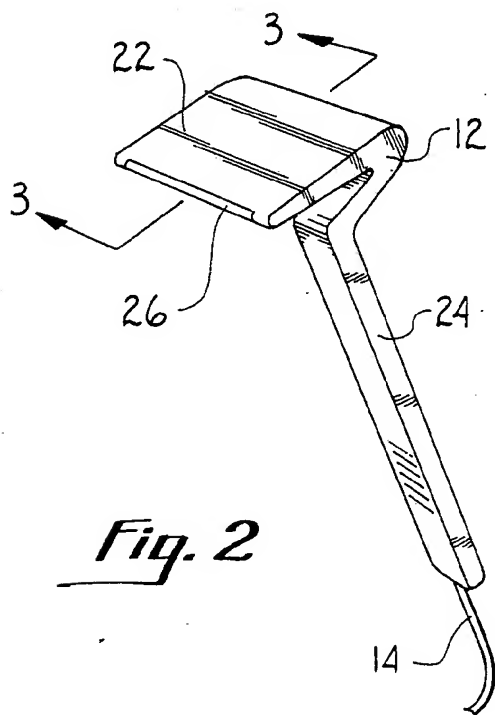
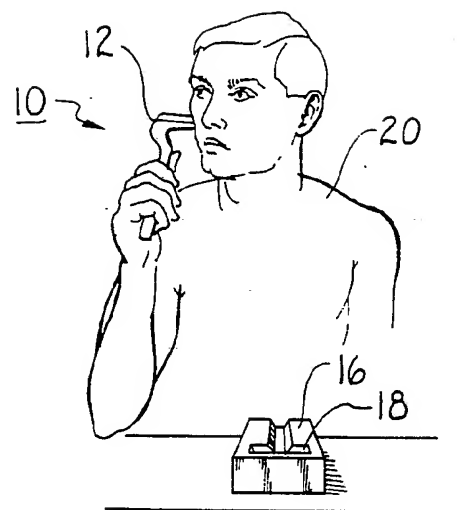
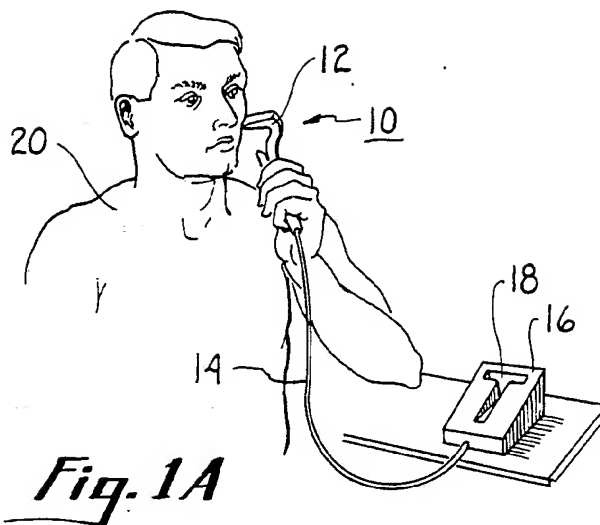
24. A method for photoablating an object which comprises the steps of:

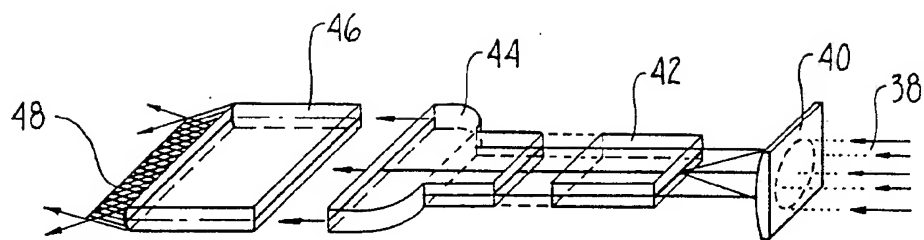
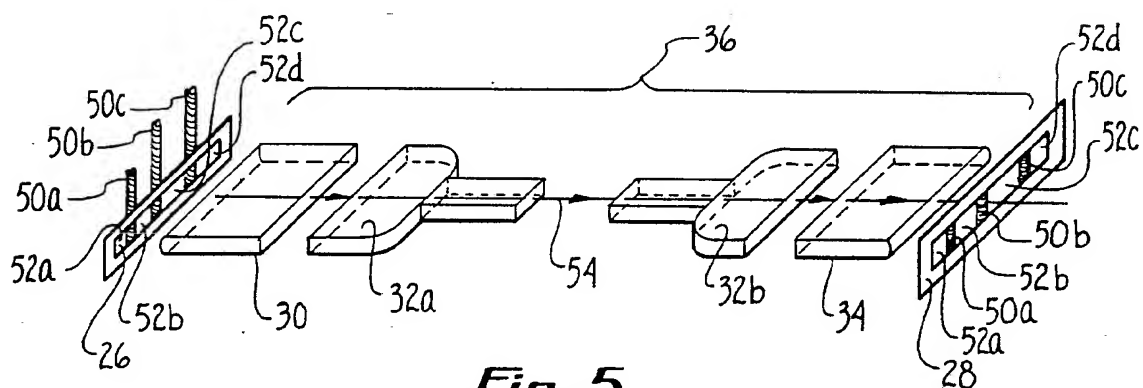
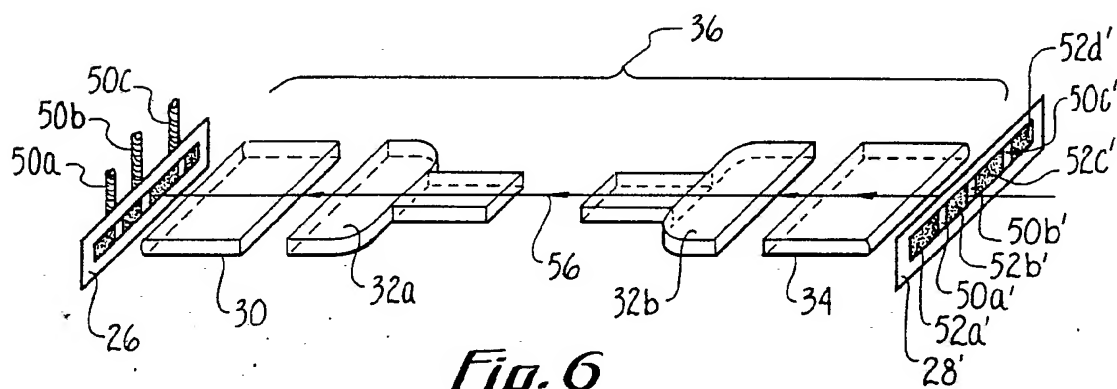
- 3 providing a device comprising a high intensity
source (58); a secondary light source (60) for
radiating light at a selected wavelength, said
6 selected wavelength being different from the
wavelength of said laser light; an aperture (26)
positionable against said object to establish a
9 picture of said aperture and said object; a filter
(28), with means for establishing said filter as a
substantial equivalent to a negative of said picture;
12 and means (36) for directing light from said high
intensity light source, and through said filter, onto
said object to photoablate said object;
15 positioning said aperture against said object;
 activating said secondary light source to
establish said filter as a negative of said picture;
18 and
 activating said high intensity light source to
direct light therefrom through said filter to
21 photoablate said object.

25. A method as recited in claim 24 wherein said
means for establishing said filter includes an image
3 recording medium (76) responsive to light of said selected
wavelength to create said negative according to said
picture, and an erasing means (62) connected to said image
6 recording medium to selectively erase said negative from
said medium, and wherein said method further comprises the
step of sequentially cycling the steps of Activating said
9 secondary light source, Activating said high intensity
light source, and Erasing said negative from said image
recording medium.

26. A method as recited in claim 24 wherein said means for establishing said filter includes an image processor responsive to light of said selected wavelength to create a signal representative of said picture, and means for activating said high intensity light source, said activating means being connected between said image processor and said high intensity light source, to radiate high intensity light from said high intensity light source according to said signal, and wherein said method further comprises the step of alternately activating said secondary light source and said high intensity light source.

27. A method as recited in claim 24 wherein said high intensity light source is a source of laser light.



*Fig. 4**Fig. 5**Fig. 6*

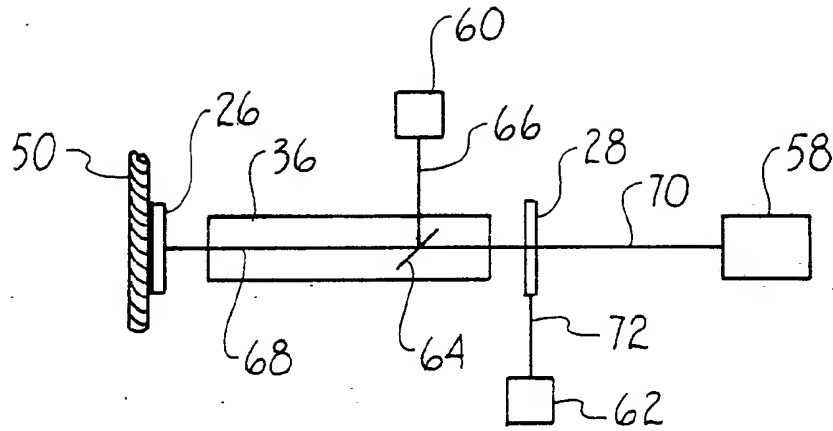


Fig. 7

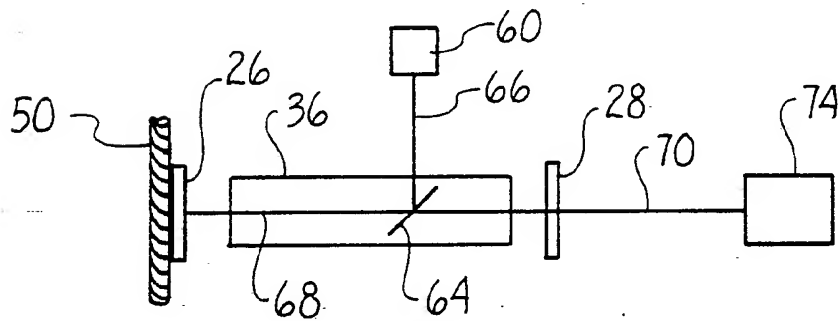


Fig. 8

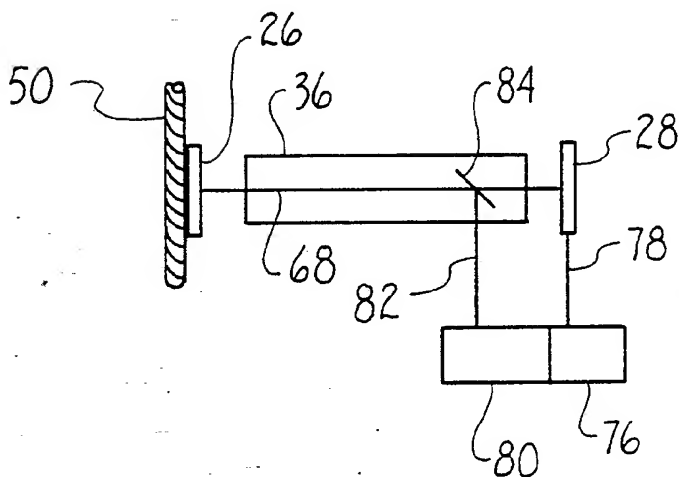


Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 92/06327

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 B23K26/06; B23K26/00; A61B17/41		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	B23K ; A61B ; B26B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	GB,A,2 221 060 (INDUSTRIAL TECHNOLOGY RESEARCH INST.) 24 January 1990 see page 1, line 1 - page 4, line 13 see abstract; claim 1; figure 1 ---	1
Y	US,A,4 978 830 (M.A. MILLERICK ET AL.) 18 December 1990	1
A	see column 2, line 30 - line 44 see column 2, line 61 - column 3, line 25 see column 3, line 28 - line 37 see column 4, line 19 - line 26 see abstract; claims 1-3,6,7,16; figures 1-6 --- -/--	2-27
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
25 JANUARY 1993	08.02.93	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	HAEGEMAN M.	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y	EP,A,0 125 692 (NEC CORPORATION) 21 November 1984	1
A	see page 3, line 1 - page 5, line 7 see page 7, line 6 - line 20 see abstract; claims 1-12; figures 1-11 ---	2-27
A	WO,A,9 106 406 (SIMON) 16 May 1991 see page 1, line 26 - line 37 see page 2, line 23 - line 34 see abstract; claim 1; figures 1-4 -----	1-27

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9206327
SA 63298

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A-2221060	24-01-90	US-A- 4918611	17-04-90
US-A-4978830	18-12-90	JP-A- 2247090	02-10-90
		US-A- 5099101	24-03-92
EP-A-0125692	21-11-84	JP-A- 59211016	29-11-84
		JP-A- 60027490	12-02-85
		US-A- 4734558	29-03-88
WO-A-9106406	16-05-91	DE-A- 3936367	08-05-91
		EP-A- 0452459	23-10-91



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/41	A1	(11) International Publication Number: WO 95/15725 (43) International Publication Date: 15 June 1995 (15.06.95)
(21) International Application Number: PCT/GB94/02682 (22) International Filing Date: 7 December 1994 (07.12.94) (30) Priority Data: 9325109.8 8 December 1993 (08.12.93) GB (71) Applicant (for all designated States except US): SLS (WALES) LIMITED [GB/GB]; Units 1 & 2, Heol Rhosyn, Dafen Industrial Estate, Llanelli, Dyfed SA14 8LX (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): CLEMENT, Richard, Marc [GB/GB]; 11 Plas Road, Rhos, Pontardawe, West Glamorgan SA8 3HD (GB). KIERNAN, Michael [GB/GB]; 89 Heol Eddwch, Seven Sisters, West Glamorgan SA10 9AW (GB). (74) Agent: AUSTIN, Hedley, William; Urquhart-Dykes & Lord, Alexandra House, Alexandra Road, Swansea, West Glamorgan SA1 5ED (GB).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: DEPILATION (57) Abstract <p>Mammalian hair is depilated using a laser source capable of emitting pulsed radiation, each pulse having a duration of 1μs to 1ms, the radiation having a wavelength in the range of 600 to 1500nm. A selected area of a patient's skin is irradiated by the pulsed radiation, the area having a plurality of irradiation zones; the laser source is successively pulsed so as to irradiate successive zones of the treatment area with the radiation, so as to destroy subdermal biological material associated with hair growth.</p>		

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Depilation

The present invention is concerned with a method of depilation of mammalian hair and also apparatus for use in the method.

U.S. Patents 3538919 and 4617926 are both concerned with depilation. These patents teach the stepwise irradiation of single hairs or hair follicles; the process described in U.S. 3538919 involves inserting a laser probe within a hair follicle and the process described in U.S. 4617926 involves inserting a single hair within a bore of a fibre optic probe. These processes are time consuming, and can lead to unnecessary discomfort to a patient.

We have now developed a method and apparatus which alleviates the above problems.

According to the present invention there is provided a method of depilation of mammalian hair, which method comprises:

- (a) providing a laser source capable of emitting pulsed radiation, each pulse having a duration of $1\mu\text{s}$ to 1ms , said radiation having a wavelength in the range of 600 to 1500nm ;
- (b) selecting a treatment area of a patient's skin to be irradiated by said pulsed radiation, said treatment area including a plurality of irradiation zones; and
- (c) successively pulsing said laser source so as to irradiate successive zones of said treatment area with said radiation, so as to destroy subdermal biological material associated with hair growth.

It is preferred that the laser source comprises either a ruby laser (wavelength 694.3nm), a neodymium YAG laser (wavelength $1.064\mu\text{m}$) or other lasers having a wavelength in the abovementioned (visible red to near infra-red) range. The selection of a laser having a wavelength in the range of 600 to 1500nm is advantageous in that radiation of this wavelength is capable of selectively destroying cells or other subdermal biological material responsible for hair growth, whilst not being substantially absorbed by surrounding cells or tissue.

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It is preferred that a laser with variable pulse duration is used. This is advantageous in facilitating irradiation of selected intensity, depending on the required application of the laser.

Advantageously, the irradiation zones are juxtaposed so as to substantially cover the treatment area. Preferably the successive irradiation involves irradiation in boustrophedon manner, so as to ensure substantially complete irradiation of the treatment area.

It is preferred that the irradiation destroys cells present at the root of individual hair follicles; optionally, the irradiation may further destroy cells present in respective bulge regions of follicles.

There is further provided by the present invention depilation apparatus for use in a method as described above, the apparatus comprising:

- (a) a laser source capable of emitting pulsed radiation, wherein each pulse has a duration of $1\mu\text{s}$ to 1ms , the radiation having a wavelength in the range of $600\text{-}1500\text{nm}$; and
- (b) means for irradiating a zone of a patient's skin with said radiation, so as to be capable of destroying biological material present in said irradiation zone, associated with hair growth.

The apparatus may advantageously further comprise means for effecting irradiation of successive zones of the patient's skin. Typically, means are provided for effecting movement of the apparatus relative to the patient's skin so as to irradiate the skin in a boustrophedon manner substantially as described above.

Claims:

1. A method of depilation of mammalian hair, which method comprises:
 - (a) providing a laser source capable of emitting pulsed radiation, each pulse having a duration of $1\mu\text{s}$ to 1ms , said radiation having a wavelength in the range of 600 to 1500nm ;
 - (b) selecting a treatment area of a patient's skin to be irradiated by said pulsed radiation, said treatment area including a plurality of irradiation zones; and
 - (c) successively pulsing said laser source so as to irradiate successive zones of said treatment area with said radiation, so as to destroy subdermal biological material associated with hair growth.
2. A method according to claim 1, wherein said laser source comprises a ruby laser having a wavelength of 694.3nm or a neodymium YAG laser having a wavelength of $1.064\mu\text{m}$.
3. A method according to claim 1 or 2, wherein said laser source has a variable pulse duration.
4. A method according to any of claims 1 to 3, wherein said irradiation zones are juxtaposed so as to substantially cover said treatment area.
5. A method according to any of claims 1 to 4, wherein said successive irradiation of said treatment area is in boustrophedon manner, so as to ensure substantially complete irradiation of said treatment area.
6. Depilation apparatus for use in a method according to any of claims 1 to 5, said apparatus comprising:
 - (a) a laser source capable of emitting pulsed radiation, wherein each pulse has a duration of $1\mu\text{s}$ to 1ms , the radiation having a wavelength in the range of 600 - 1500nm ; and
 - (b) means for irradiating a zone of a patient's skin with said radiation, so as to be capable of destroying biological material present in said irradiation zone, associated with hair growth.

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7. Apparatus according to claim 6, which further comprises means for effecting irradiation of successive zones of a patient's skin.
8. Apparatus according to claim 6 or 7, which includes means for effecting movement of said apparatus relative to said patient's skin so as to irradiate said skin in a boustrophedon manner.

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/41

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,92 19165 (VICTORIA UNIVERSITY OF MANCHESTER) 12 November 1992 see page 2, paragraph 3 ---	6,7
A	US,A,5 059 192 (ZAIAS) 22 October 1991 see column 3, line 39 - line 40 ---	6
A	US,A,4 718 416 (NANAUMI) 12 January 1988 see column 3, paragraph 1 ---	8
A	US,A,5 065 515 (IDEROSA) 19 November 1991 see column 2, line 42 - line 45 see column 4, line 34 - line 39 -----	8

☐ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

28 March 1995

Date of mailing of the international search report

10.05.95

Name and mailing address of the ISA

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Fax (+31-70) 340-3016

Authorized officer

Barton, S

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB94/02682

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-5
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1(iv)
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

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2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

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- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

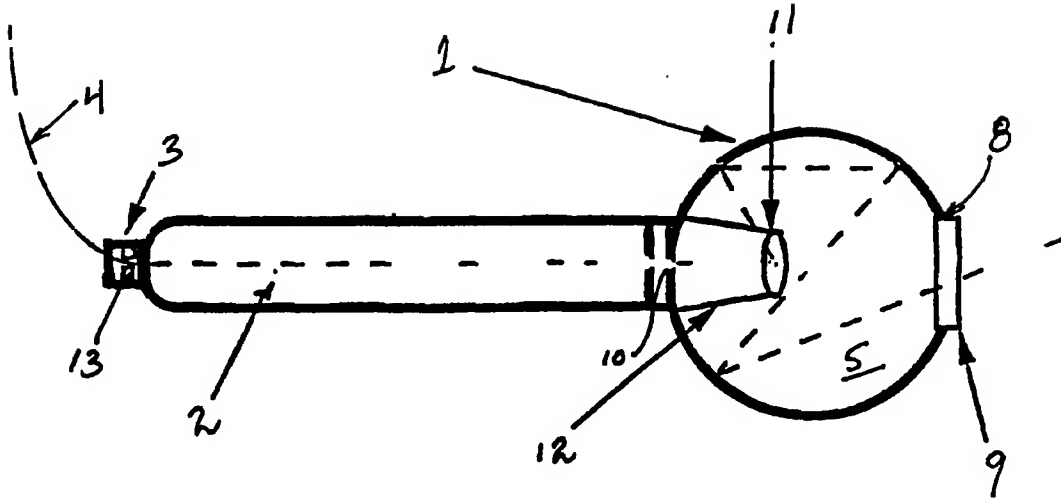
Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9219165	12-11-92	AU-A- 1981992	21-12-92
US-A-5059192	22-10-91	NONE	
US-A-4718416	12-01-88	JP-A- 60148567	05-08-85
US-A-5065515	19-11-91	NONE	

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(21) International Application Number: PCT/US95/06686 (22) International Filing Date: 25 May 1995 (25.05.95) (30) Priority Data: 08/248,918 25 May 1994 (25.05.94) US (71) Applicant: THE GOVERNMENT OF THE UNITED STATES OF AMERICA, represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES [US/US]; 200 Independence Avenue, S.W., Washington, DC 20201 (US). (72) Inventors: SMITH, Paul, D.; 3201 Harness Creek Road, Annapolis, MD 21403 (US). COLE, John; 9400 Wooden Bridge Road, Potomac, MD 20854 (US). HARRINGTON, Frank, S.; 2 David Lee Court, Catonsville, MD 21228 (US). BERNSTEIN, Eric, F.; 1321 Grenoa Road, Wynnwood, PA 19096 (US). (74) Agents: GZYBOWSKI, Michael, S. et al.; Lowe, Price, LeBlanc & Becker, Suite 300, 99 Canal Center Plaza, Alexandria, VA 22314 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>
(54) Title: IRRADIANCE ATTACHMENT FOR AN OPTICAL FIBER TO PROVIDE A UNIFORM LEVEL OF ILLUMINATION ACROSS A PLANE		
		
(57) Abstract <p>An irradiation attachment for an optical fiber (4) which provides an output of light that has a highly uniform intensity. The device includes a hollow spherical shell (1) having a diffusive reflective surface or target (11) supported (12) therein. Light is directed into the hollow spherical shell (1) so that it reflects off the diffusive reflective surface or target (11). The reflected light is internally reflected off the inner surface of the hollow spherical shell (1) several times before passing through an output aperture (8). As a result of the internal reflection within the hollow spherical shell (1), the light leaving the device has a highly uniform intensity. The device is particularly useful for photodynamic therapy.</p>		

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IRRADIANCE ATTACHMENT FOR AN OPTICAL FIBER TO PROVIDE
A UNIFORM LEVEL OF ILLUMINATION ACROSS A PLANE

Technical Field

The present invention relates to photodynamic therapy methods and devices. More particularly, the present invention is directed to devices which provide and deliver a highly uniform irradiation beam which is particularly suitable for photodynamic therapy.

Background Art

Photodynamic therapy (PDT) exploits the selective uptake of a photosensitizer in tumors and other hyperproliferative target tissues. Since the difference between target tissue uptake of photosensitizer and that of normal tissue is at best only marginal, uniform delivery of light is crucial to attain optimal photodynamic effect. Some degree of selectivity may be achieved by simply aiming the light beam at the desired target tissue, but to truly offer selectivity of action on target tissue versus adjacent or intermixed normal tissue, selective uptake of dye into target tissue and uniform delivery of light is required. Variations in applied light intensity may result in certain areas within a treatment field receiving over or under dosing. Thus, tumor tissue may be inadvertently spared destruction if present in an area of under treatment, while normal tissue may be destroyed if light intensity is focally increased in a certain area.

Clinical applications of PDT have used free optical fibers as well as diffusing lenses to administer laser

light to treatment areas. Light delivery is usually accomplished with an argon-pumped dye laser using a single wavelength of light. This allows for easy calculation of delivered light dose and an estimate of photodynamic effect.

The selective uptake of dihematoporphyrin ether (DHE) and other photosensitizers within tumors, or other rapidly proliferating tissues, is the basis for most of the therapeutic benefit of PDT. Although photodynamic effect may be directed to specific areas by selective placement of the treatment beam, this affords little benefit in treating most diseases over other descriptive modalities. Selective destruction of target tissue over adjacent, or even intermixed, normal tissue depends upon selective uptake of photosensitizer in target tissue as compared to normal tissue. This has been shown to occur with numerous tumors and other proliferative disorders in vivo, with a variety of photosensitizers. Relative differences in the uptake of DHE into target tissue versus skin, have been shown to be 1.08, 1.8, 2.2, 3.9 and 4.2 in various animal models. Although newer photosensitizers such as the phthalocyanines and 5-ALA-induced protoporphyrin IX may result in even higher relative differences in photosensitizer uptake in target tissue, normal tissues still retain significant amount of photosensitizer in most cases.

Tissue DHE content is a function of the administered DHE and its degree of retention within various tissues. Because differences between target tissue DHE content and normal structures is relative and not absolute, uniform light delivery is imperative to ensure destruction of tumors while sparing normal healthy tissue.

Disclosure of the Invention

It is accordingly one object of the present invention to provide device for producing and delivering a highly uniform irradiation beam of light.

5 Another object of the present invention is to provide a light delivery device which is particularly useful for photodynamic therapy.

10 It is a further object of the present invention to provide a device which produces a beam of light which has a highly uniform illumination throughout the entire field thereof.

A further object of the present invention is to produce a photodynamic light delivery device which can be in direct contact with a target situs during use.

15 A still further object of the present invention is to provide a method of photodynamic therapy wherein a light delivery device which produces a highly uniform beam of light is in direct contact with a target situs during use.

20 According to these and further objects of the present invention which will become apparent as the description thereof proceeds, the present invention provides a light delivery device which includes:

25 a hollow spherical shell which defines a cavity therein and includes a diffusive reflective inner surface;

an input aperture formed within the hollow spherical shell for passing a beam of light into the cavity;

30 a diffusive reflective surface within the cavity which is supported away from the inner surface of the hollow spherical shell and aligned with the input aperture, whereby light which passes through the input aperture into the cavity is reflected off the diffusive reflective surface before reaching the diffusive reflective inner surface of the spherical shell; and
35

an output aperture formed within the hollow spherical shell through which only light that is reflected off the diffusive reflective inner surface exits the hollow spherical shell.

5 The present invention further provides a method of applying photodynamic therapy to a target situs which involves:

a) providing light delivery device, the light delivery device including:

10 a hollow spherical shell which defines a cavity therein and includes a diffusive reflective inner surface,

an input aperture formed within the hollow spherical shell for passing a beam of light into the cavity,

15 a diffusive reflective surface within the cavity which is supported away from the inner surface of the hollow spherical shell and aligned with the input aperture, whereby light which passes through the input aperture into the cavity is reflected off the diffusive reflective surface before reaching the diffusive reflective inner surface of the spherical shell, and

20 an output aperture formed within the hollow spherical shell through which only light that is reflected off the diffusive reflective inner surface exits the hollow spherical shell;

25 b) positioning the output aperture of the light delivery device near a target situs; and

c) delivering light into the light delivery device and therethrough to the target situs.

30 Brief Description of Drawings

The present invention will be described with reference to the attached drawings which are given by way of non-limiting examples only, in which:

Figure 1a is a schematic diagram of an integrating sphere according to the present invention.

Figure 1b is an exploded schematic diagram of the integrating sphere of Figure 1a.

5 Figure 2 is a plot of the intensity output of a free cleaved optical fiber.

Figure 3 is a plot of the intensity output of an optical fiber having a diffusing lens on the end thereof.

10 Figure 4 is a plot of the intensity of the integrating sphere of the present invention measured just outside the aperture (closed circles) and just inside the aperture (open circles).

15 Figure 5 shows eschars formed on guinea pigs which were given photodynamic therapy utilizing a free optical fiber (top) and an integrating sphere according to the present invention (bottom).

Best Mode for Carrying out the Invention

20 The present invention is directed to a device which allows for the delivery of a very uniform beam of laser light. The device, referred to herein as an integrating sphere because of its shape, provides exceptional uniform illumination as compared to light output from a diffusing lens and a free optical fiber. The integrating sphere of the present invention is also comparable to a free
25 optical fiber in its ability to produce a uniform eschar on the skin of guinea pigs given dihematoporphyrin ether (DHE). Test results indicate that the integrating sphere of the present invention can allow for optimization of desired effects of PDT, while significantly decreasing
30 over or under dosing problems associated with inhomogeneity of the treatment beam.

The integrating sphere of the present invention provides a simple means of delivering a highly uniform beam of light for use with experimental or clinical PDT.

Since, in use, the sphere is placed directly against the tissue to be treated, possible errors in beam height due to patient movement are virtually eliminated. The present invention further decreases problems associated with shielding, while allowing quick and easy application of light by simply applying the device over the desired treatment area. Moreover, the desired photodynamic effect is optimized because of the highly uniform beam of light produced by the device.

The integrating sphere of the present invention includes a handle and a hollow sphere attached to the handle. The handle receives an optical fiber through which laser light is directed into the inside of the hollow sphere. The light enters the hollow sphere and is diffused by and reflected off of a reflector or target supported in the hollow sphere. The reflected light is then internally reflected numerous times off of the inner surface of the hollow sphere which is provided with a diffusive reflective coating. After internally reflecting within the hollow sphere, the light emerges through an aperture formed within the wall of the hollow sphere. The emerging light has high degree of field uniformity resulting from the internal reflection within the hollow sphere.

Tests conducted during the course of the present invention have demonstrated that significant variability in light beam homogeneity may exist with some light delivery systems which are presently being used to administer PDT. Although such delivery systems may be manipulated by changing optical fiber orientation and laser output to attain a more uniform light beam, these manipulations are not consistent. In addition, undesirable changes in light uniformity may occur with movement of optical fibers or changes in laser output characteristics. The integrating sphere of the present

invention delivers a uniform beam of light in spite of variabilities in laser output characteristics or changes in laser optical fiber position. In the integrating sphere of the present invention, only the light intensity
5 would change if the output of the laser varied during treatment.

Figure 1a is a schematic diagram of an integrating sphere according to the present invention. As shown in Fig. 1a the device includes a spherical shell 1, a handle
10 2, a optical fiber support 3, and a optical fiber 4. The spherical shell 1 has a diffusive reflective inner surface and is preferably made from two half shells (Fig. 1b), which define spherical cavity 5 when attach together. Figure 1b is an exploded schematic diagram of
15 the integrating sphere of Figure 1a. As shown in Figure 1b, the two halves 7a and 7b of the spherical shell 1 are preferably held together by cooperating internal and external threaded portions 6a and 6b which are shown in Fig. 2b. In an alternative embodiment, the spherical
20 shell halves can include flanges in place of the threaded portions 6a and 6b which can be secured together by mechanical fasteners, e.g., screws, bolts, clips, etc. In a further embodiment the threaded portions 6a and 6b could be replaced by a bayonet mounting structure. The
25 two half shells 7a and 7b should be made from a solid material which is sufficiently heat resistant. Metals are preferred. Aluminum is more preferred because of its light weight.

The ability to separate the shell halves 7a and 7b from each other allows for easy cleaning or repair should
30 this be necessary. The distal hemisphere (shell half 7b) of the spherical shell 1 includes an output port 8 through which a treatment beam exits. The output port aperture may be covered with a transparent, e.g., glass,
35 window to prevent dust from entering the spherical cavity

5. The diameter of the output port 8 can be as large as the diameter of the spherical shell 1, or as small as desired for a particular application. The shape of the output port need not be circular. However, a circular output port is suitable for general application. The proximal hemisphere (shell half 7b) is attached to a hollow handle 2. The hollow handle 2 is preferably made from a material which is sufficiently heat resistant. Metals are preferred. Aluminum is more preferred because of its light weight. The proximal hemisphere can be attached to the handle 2 by welding, cementing, epoxying, mechanical means, e.g, threaded connection, or any other suitable means.

At the center of the area of the spherical shell 1 where the handle 2 is attached there is a small aperture 10. As discussed in more detail below, the aperture 10 allows light to enter the spherical cavity 5.

A reflector or target 11 is located within the spherical cavity 5 and aligned with the aperture 10. The reflector or target 11 is supported away from the aperture 10 by a plurality of supports or stand-offs 12. The reflector or target 11 has a diffusive reflective surface which faces the aperture 10. The diffusive reflective surface of the reflector on target 11 can be planar, or convex. The distance between the aperture 10 and the reflector or target 11 should be adjusted so that the light entering the spherical shell 1 undergoes a maximum amount of internal reflection. Generally it has been found that the distance between the aperture 10 and reflector or target 11 should be between about one to one-sixth the radius of the spherical shell 1 for a planar diffusive reflective surface and less, e.g. one-tenth to one-half the radius of the spherical shell 1 for a convex diffusive reflective surface. It is to be understood that the reflector or target 11 should be

appropriately sized and positioned so as to prevent (i.e., block) light delivered by optical fiber 4 from passing directly through the output port 8. According to a preferred embodiment, the reflector or target 11 is circular.

A optical fiber support 3 is attached to the proximal end of the handle 2. The optical fiber support 3 acts as a connector for optical fiber 4 which is received in and supported by the optical fiber support 3. The optical fiber support 3 includes a through-bore having a gasket or bushing 13 therein, e.g., an O-ring, into which an end of the optical fiber 4 can be inserted. Additional gaskets or bushings can be provided within the handle 2 to receive and support the optical fiber 4 in proper alignment. The optical fiber support 3 can be attached to the end of the handle 2 by welding, cementing, epoxying, mechanical means, e.g., threaded connection, press fit, or any other suitable means. The optical fiber support 3 can be made from any material which is mechanically strong and has a sufficient heat resistance. Metals are preferred. Aluminum is more preferred because of its light weight.

In a preferred embodiment, the optical fiber 4 is held by the optical fiber support 3 so that an end thereof is positioned about half-way between the reflector or target 11 and the wall of the spherical shell 1. The entire inside of the spherical shell 1, the stand-offs 12 and reflector or target 11 are all coated with a diffusive reflective coating. Such a diffusive reflective coating can be applied by any convenient means. According to one embodiment of the present invention, the diffusive reflective coating was applied using an air-brush technique. A preferred diffusive reflective coating found to be useful for purposes of the present invention was a Kodak analytic standard white

diffusive reflective coating in an ethanol base (Eastman Kodak Co., Rochester, NY). However, any known diffusive reflective coating material could be used according to the present invention.

5 All light coming from the integrating sphere's aperture 10 is internally reflected. In use the output port 8 (or window 9 of the integrating) sphere can be placed flush in contact with a target tissue. This eliminates shielding so that only the center of a beam of
10 light is used.

According to the present invention the size of the spherical shell 1 and output port 8 can be chosen as appropriate to treat lesions of different sizes. In this regard, changing from one spherical shell size to another
15 can be easily accomplished by providing a detachable connection between the proximal hemisphere (half shell 7a) of the spherical shell 1 and the handle 2, e.g., a mechanical connection such as a threaded connection, a bayonet mounting structure, a luer lock structure, or the
20 like.

Features and characteristics of the present invention will be illustrated by the following examples to which the present invention is not to be considered limited. In the examples and throughout percentages are
25 by weight unless otherwise indicated.

Example 1

In this example, the uniformity of three different delivery devices was tested. Green 514 nm light was delivered using an argon laser (model PRT 100, Coherent
30 Inc., Palo Alto, CA) coupled to a 600 micron, fused silica, flat end optical fiber (model PCS 600, Q.P.C., Inc., Plainfield, N.J.). Laser output was measured at the optical fiber tip using a power meter (model 210;

Coherent, Inc., Pal Alto, CA) resulting in a surface dose rate of 30 mW/cm².

5 The light was delivered by three methods: a non-optimized flat-end cleaved optical fiber, a non-optimized 600 μ m microlens (Laser Therapeutics, Inc., Buelton, CA), and an integrating sphere according to the present invention. Light was delivered in a 1.0 cm diameter circle in the first 2 cases. The integrating sphere used here had a circular aperture with a diameter of 1.0 cm, 10 and delivered light to the test area when placed against the test site.

Light output measurements were taken using a photodiode clamped in place on a movable vice grip. The vice was moved in 0.5 to 1.0 mm increments along the 15 greatest diameter (1.0 cm) of the light field, for each of the three modes of light delivery used. The photodiode was connected to a computer based light monitoring system. The monitoring system produced numerical readouts of field uniformity for each of the 20 three light delivery methods used. All readings were carried out within a few hours of each other in an identical fashion. Numerical results were plotted on a graph for comparison. Measurements were carried out for the integrating sphere just outside of the aperture for 25 comparison with the other readings, and just inside the aperture to duplicate the actual treatment conditions in which the sphere is used.

Figure 2 is a plot of the intensity output of a free cleaved optical fiber. As seen from Fig. 2, the light 30 output across the 1.0 cm diameter circle produced by the free optical fiber varied significantly across the largest diameter of the field. Across the center 0.4 cm of the 1.0 cm beam, light intensity varied by as much as 21%.

Figure 3 is a plot of the intensity output of an optical fiber having the diffusing lens on the end thereof. As seen in Fig. 3, the light output across the 1.0 cm field produced by 600 μ m microlens also varied significantly across the largest diameter of the field. Across the center 0.4 cm, light intensity varied by more than 60%.

Figure 4 is plot of the intensity of the integrating sphere of the present invention measured just outside the output port (closed circles) and just inside the output port (open circles). As seen in Fig. 4, the integrating sphere delivered a highly uniform beam varying by only 4% across the center 0.4 cm of the light beam. When measuring light intensity just within the output port of the sphere, as would be the case when placing the sphere against target tissue, the beam intensity varied by less than 10% over the entire 1.0 cm diameter. Across the center 4.0 mm of this field, light intensity only varied by less than 2%.

Example 2

In this example, five adult Hartley albino guinea pigs (0.45-0.55 kg) were used for testing purposes. Hair removal was accomplished 24 hours after photosensitizer administration by shaving with animal clippers and subsequent application of a depilatory lotion which was allowed to dry for 15 minutes then was completely removed with warm water. Hair removal was complete with little or no erythema. Depilation was accomplished 24 hours prior to laser light treatments. Hair removal and light treatment were carried out after anesthesia with intraperitoneal ketamine hydrochloride (90 mg/kg) and xylazine (5 mg/kg) administered intraperitoneally. After photosensitizer administration and until the experiments were completed, guinea pigs were housed in reduced

lighting and shielded from direct light. Post treatment, guinea pigs were individually housed to prevent them from tampering with each other's treatment sites.

5 Photofrin II® (Quadra Logics Technologies, Vancouver, British Columbia) brand of dihematoporphyrin ethers (DHE), a purified product of hematoporphyrin derivative (HPD), in an isotonic saline solution at a concentration of 2.5 mg/ml was used as the photosensitizer. Lyophilized DHE was kept in the dark at 10 -70°C until just before use, and reconstituted with water resulting in an isotonic solution. DHE was administered intraperitoneally at 10 mg/kg two days before laser treatment.

15 Treatment sites were located on the backs of all guinea pigs in two linear arrays of 3 sites. Each animal had a total of 6 sites treated, 3 on the left side and 3 on the right. Skin surface temperature was monitored throughout treatment. Light doses of 10, 20, and 30 J/cm² were delivered to all 3 guinea pigs. Each animal 20 received 3 sites treated to the above doses with an open optical fiber on one side, and with the integrating sphere on the contralateral side. The experiment was repeated in triplicate. All treatment doses were delivered in anatomically identical locations on the left 25 and right sides of each guinea pig. After light administration treatment sites were lightly marked in indelible black ink. Two animals were not given photosensitizer, otherwise they were treated in an identical manner.

30 Treatment sites were evaluated for eschar formation on day 7. This time period was determined to correspond to maximal visible damage. Lesions were only compared with those on a given animal to control for variation in absorption of HPD between animals. Treatment sites were 35 photographed on day 7, with a ruler to allow

standardization of treatment sizes. Photographs were then placed in front of a video camera and digitized by a computer. Digitized images were then subject to analysis of eschar size in treatment areas as computed using the digital imaging program. These values were compared to ideal area of illumination which were 1 cm circles in each case. Circles made by the free optical fiber were made to be exactly 1 cm in diameter by adjusting the treatment height of the optical fiber. The integrating sphere had an output port forming a circle 1 cm in diameter, which was placed directly in contact with the skin of each guinea pigs.

Area of eschar as calculated using a computer based graphics system are shown in Table 1. Eschars more closely corresponded with the size of the treatment field when using the integrating sphere than when using the free optical fiber. Eschar sizes were compared to an ideal 1.0 cm² circle, which has an area of 0.785 cm². Treatment sites varied from the ideal circle by an average of only 12.8% when treated with the integrating sphere, versus 40.7% with the free optical fiber. Small eschars were produced centrally by the free optical fiber at a light dose of 10J/cm² with the free optical fiber but not with the integrating sphere. This dose has been shown to be below the threshold for eschar formation in guinea pig skin when using uniform treatment beams. Uniform eschars were produced with the integrating sphere at light dose of 20 and 30 J/cm².

Figure 5 shows eschars formed on guinea pigs which were given photodynamic therapy utilizing a free optical fiber (top) and an integrating sphere according to the present invention (bottom). Sites treated with the free optical fiber showed increasing areas of eschar as the light dose increased. Guinea pigs receiving light and no DHE showed no evidence of eschar formation at any dose.

Temperatures increased by no more than 2.9°C during treatment.

The relevant data from the tests performed in Example 2 are presented below in Table 1.

5 **TABLE 1. Photodynamic effect of integrating sphere versus free optical fiber on guinea pig skin**

<u>Light dose</u>	<u>Sphere 1</u>	<u>Fiber 1</u>	<u>Sphere 2</u>	<u>Fiber 2</u>	<u>Sphere 3</u>	<u>Fiber 3</u>
10 J/cm ²	0*(0%) [†]	.30(38%)	0(0%)	.15(19%)	0(0%)	.15(19%)
20 J/cm ²	.86(109%)	.51(65%)	.78(100%)	.64(82%)	.98(125%)	.50(64%)
30 J/cm ²	.86(109%)	.92(124%)	.82(105%)	.95(121%)	1.0(129%)	.89(114%)

10 In Table 1, areas of eschar produced by light administration to guinea pigs given 10 mg/kh DHE, as calculated by computer graphics program are expressed in cm². Results are paired with designations 1, 2 and 3 referring to treatments done on either side of each of the three guinea pigs. Each guinea pig received a total of six reaction sites: three on the first side using the

15 integrating sphere, and three on the other side using the free optical fiber. "Sphere" refers to the side treated with the integrating sphere and "Fiber" refers to the side treated with the free optical fiber to the light doses shown.

20 The expected area for a 1 cm diameter circle using πR^2 is .785 cm². Each area (in parentheses) is expressed as a percentage of this expected value.

25 From the above, it can be seen that the integrating sphere of the present invention provides a highly uniform illumination beam, which is particularly applicable to photodynamic therapy. In this regard, the present invention further provides additional advantages such as elimination of required shielding, and quick and easy application of light over a desired treatment site.

Beyond phototherapy procedures, the integrating sphere of the present invention can be used in any application in which a highly uniform illumination field is required, such as optical examination and imaging.

5 Although the present invention has been described with reference to particular means, materials and embodiments, from the foregoing description, one skilled in the art can easily ascertain the essential characteristics of the present invention and various changes and modifications may be made to adapt the
10 various uses and characteristics without departing from the spirit and scope of the present invention as described by the claims which follow.

Claims

1. A light delivery device which comprises:
a hollow spherical shell which defines a cavity therein and includes a diffusive reflective inner surface;
5 an input aperture formed within said hollow spherical shell for passing a beam of light into said cavity;
a diffusive reflective surface within said cavity which is supported away from the inner surface of said
10 hollow spherical shell and aligned with said input aperture, whereby light which passes through said input aperture into said cavity is reflected off said diffusive reflective surface before reaching the diffusive reflective inner surface of said spherical shell; and
15 an output aperture formed within said hollow spherical shell through which only light that is reflected off said diffusive reflective inner surface exits said hollow spherical shell.
2. A light delivery device according to claim 1, wherein said output aperture is covered by a transparent window.
3. A light delivery device according to claim 1, wherein said input and output apertures are diametrically opposed from one another.
4. A light delivery device according to claim 1, wherein said diffusive reflective surface is supported from said inner surface of said hollow spherical shell by a plurality of supports.

5. A light delivery device according to claim 1, wherein said diffusive reflective surface is planar.

6. A light delivery device according to claim 1, wherein said diffusive reflective surface is convex.

7. A light delivery device according to claim 1, wherein said hollow spherical shell comprises two half shell portions which are connected together.

8. A light delivery device according to claim 7, wherein said two half shell portions included cooperating threaded portions by which said two half shell portions can be connected together.

9. A light delivery device according to claim 1, wherein said hollow spherical shell is attached to a handle.

10. A light delivery device according to claim 9, wherein said handle is detachable to said hollow spherical shell.

11. A light delivery device according to claim 9, wherein said handle is hollow.

12. A light delivery device according to claim 11, wherein an optical fiber support is connected to said handle.

13. A light delivery device according to claim 12, wherein said optical fiber support is connected to said handle at an end thereof which is opposed to said hollow spherical shell.

14. A light delivery device according to claim 12, wherein said optical fiber support includes a gasket means for receiving and securing an optical fiber.

15. A light delivery device according to claim 5, wherein said diffusive reflective surface is supported away from the inner surface of said hollow spherical shell by a distance which is between about one to one-sixth a radius of said hollow spherical shell.

16. A light delivery device according to claim 6, wherein said diffusive reflective surface is supported away from the inner surface of said hollow spherical shell by a distance which is between about one-tenth to one-half a radius of said hollow spherical shell.

17. A light delivery device according to claim 1, wherein said hollow spherical shell is made from a metal and said diffusive reflective inner surface of said hollow spherical shell comprises a diffusive reflective coating.

18. A method of applying photodynamic therapy to a target situs which comprises:

a) providing light delivery device, said light delivery device including:

5 a hollow spherical shell which defines a cavity therein and includes a diffusive reflective inner surface,

10 an input aperture formed within said hollow spherical shell for passing a beam of light into said cavity,

a diffusive reflective surface within said cavity which is supported away from the inner surface of said hollow spherical shell and aligned with said input

aperture, whereby light which passes through said input
15 aperture into said cavity is reflected off said diffusive
reflective surface before reaching the diffusive
reflective inner surface of said spherical shell, and
an output aperture formed within said hollow
spherical shell through which only light that is
20 reflected off said diffusive reflective inner surface
exits said hollow spherical shell;
b) positioning said output aperture of said light
delivery device near a target situs; and
c) delivering light into said light delivery device
25 and therethrough to said target situs.

19. A method of applying photodynamic therapy to a
target situs according to claim 18, further comprising
providing the output aperture with a transparent window
and placing said transparent window near the target situs
5 in step b).

20. A method of applying photodynamic therapy to a
target situs according to claim 19, wherein said window
is placed against the target situs in step b).

1 / 3

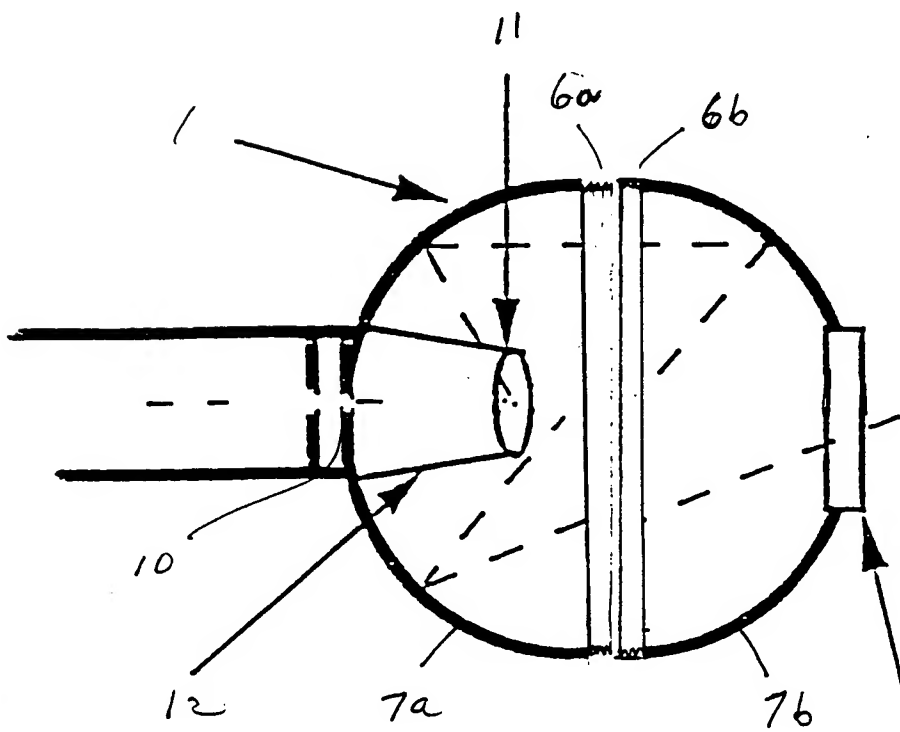
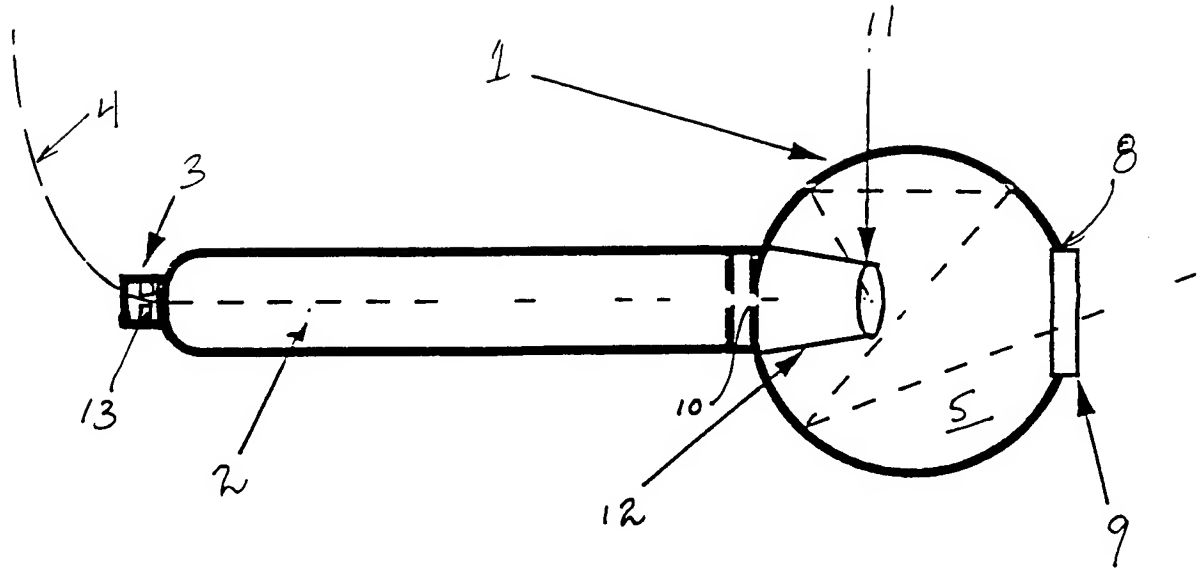


Fig. 1b

Fig. 2

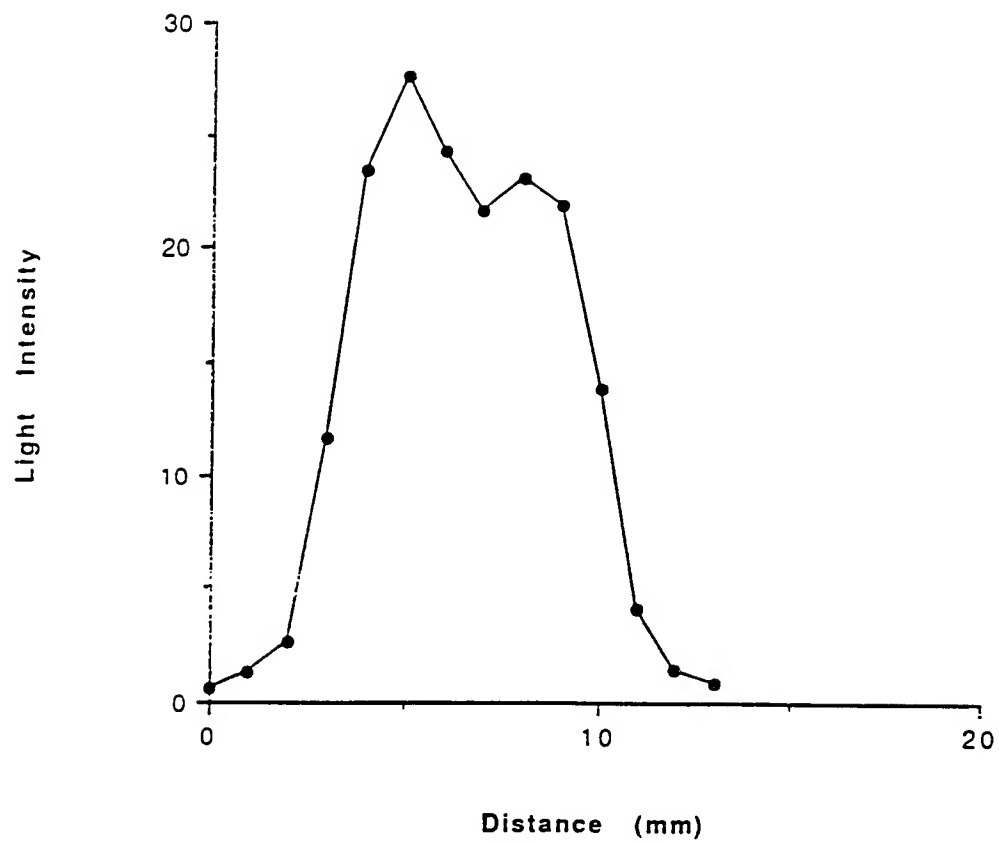


Fig. 3

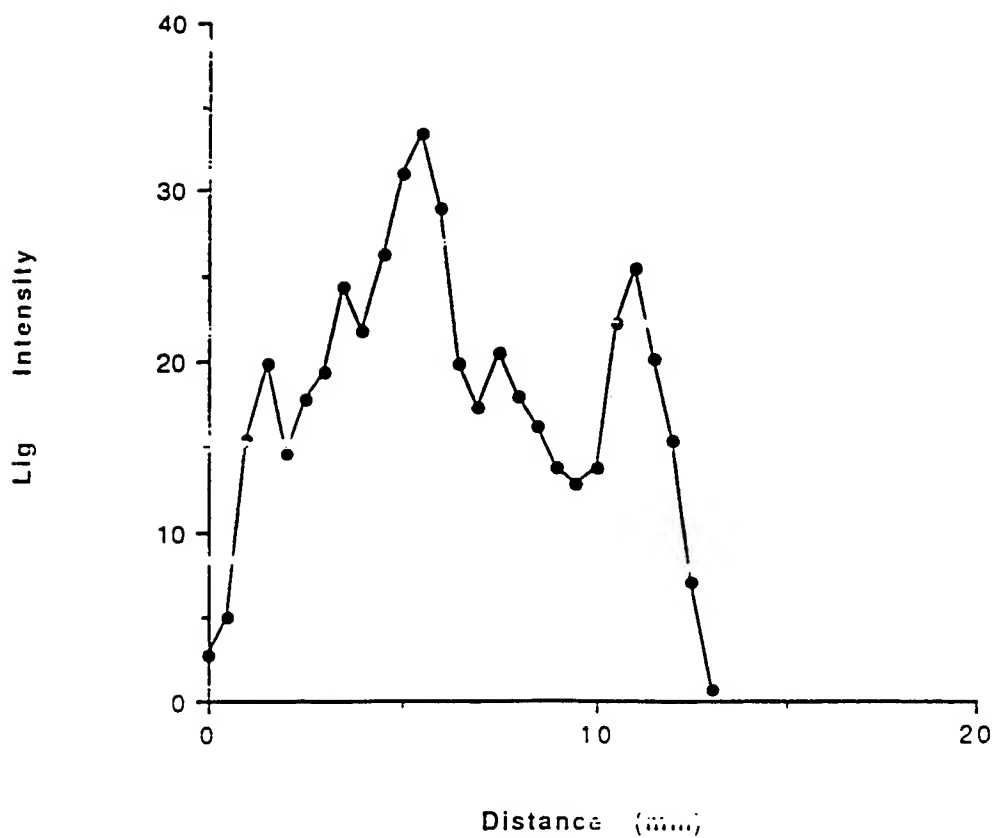


Fig. 4

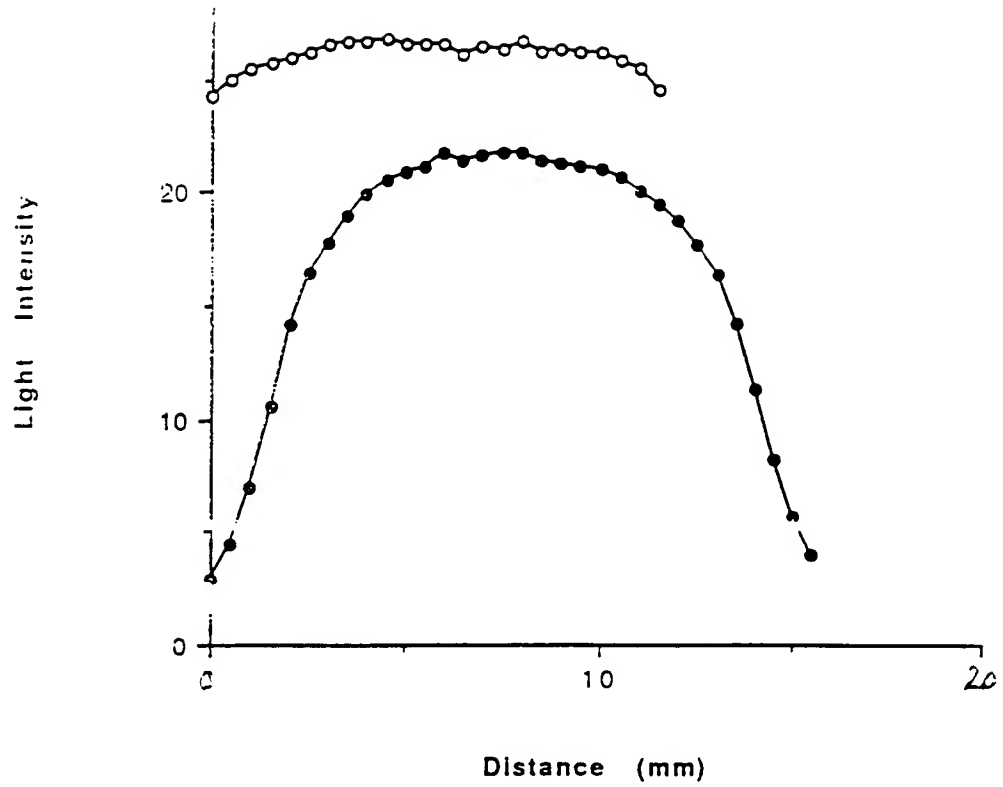
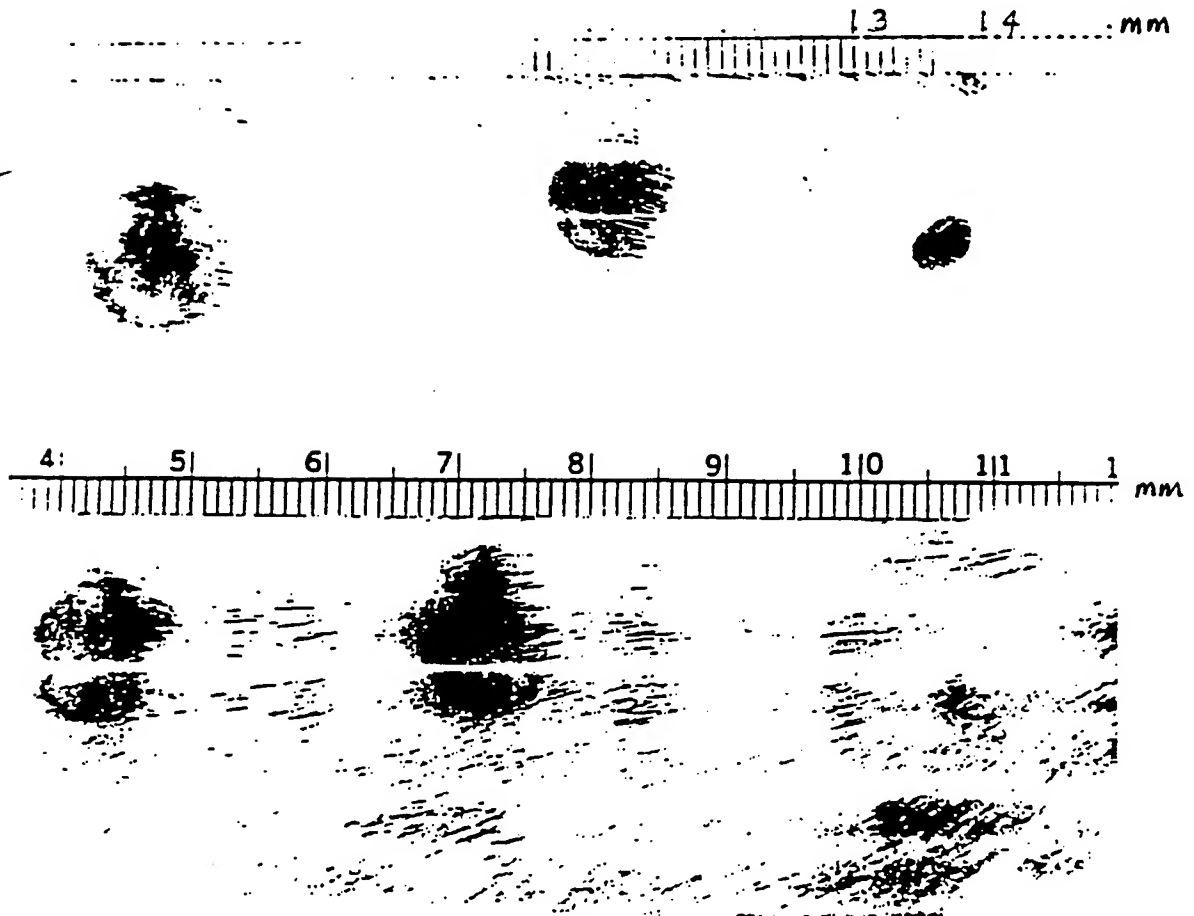


Fig. 5



A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G02B5/02 A61N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 G02B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US,A,5 309 339 (R.H.WEBB) 3 May 1994 see the whole document	1,5,17
Y		2-4,6, 18-20
Y	--- WO,A,90 00420 (A.C.ROWLAND ET AL.) 25 January 1990 see page 1; figures 1-5 see page 10 - page 15 -----	2-4,6, 18-20

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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US-A-5309339	03-05-94	NONE	
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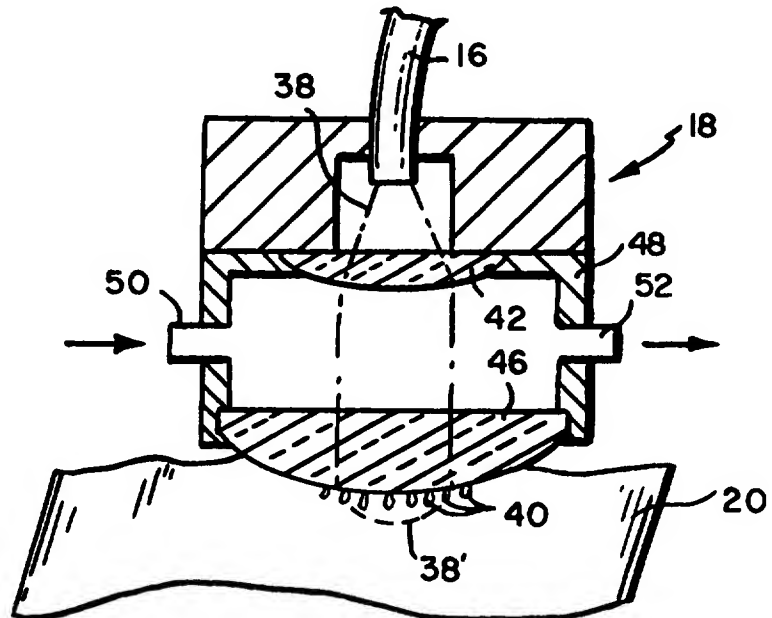
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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			(43) International Publication Date: 8 August 1996 (08.08.96)
(21) International Application Number: PCT/US96/01235 (22) International Filing Date: 31 January 1996 (31.01.96) (30) Priority Data: 08/382,122 1 February 1995 (01.02.95) US 08/593,565 30 January 1996 (30.01.96) US (71) Applicant: THE GENERAL HOSPITAL CORPORATION [US/US]; 55 Fruit Street, Boston, MA 02114 (US). (72) Inventors: ANDERSON, R., Rox; 399 Marrett Road, Lexington, MA 02173 (US). GROSSMAN, Melanic; Apartment 7K, 2 Hawthorne Place, Boston, MA 02114 (US). FARINELLI, William; 2 Elliott Street, Danvers, MA 01923 (US). (74) Agent: KRANSDORF, Ronald, J.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).			(81) Designated States: CA, CN, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: HAIR REMOVAL USING OPTICAL PULSES

(57) Abstract

A method and apparatus for simultaneously effecting the removal of multiple hairs from a skin region by using light energy to destroy hair follicles in the region. Light energy is applied to the region through an applicator which converges the light energy to enhance destruction of desired portions of the follicles, is preferably pressed against the skin region to deform the upper layers of the skin reducing the distance from the skin surface to portions of hair follicles which are to be destroyed, including the bulge and papilla of the follicles, and which applicator is preferably cooled to minimize or eliminate thermal damage to the epidermis in the region being irradiated. Parameters for the irradiation, including pulse duration, are selected to effect complete damage of desired portions of the hair follicles in the region with minimal damage to surrounding tissue and to the patient's epidermis.



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HAIR REMOVAL USING OPTICAL PULSES

Background

This invention relates to methods and apparatus for hair-removal using optical radiation.

5 Excess hair (hypertrichosis) and/or unwanted hair are common dermatological and cosmetic problems, and can be caused by heredity, malignancy, or endocrinologic diseases, for example hirsutism (i.e., excess hair due to hormones such as androgens). Hair can be temporarily removed using a number of techniques including wax epilation, depilatory creams, and, of course, shaving. Alternatively, hair can be more permanently removed using electrolysis;
10 this process involves insertion of a current-carrying needle into each hair follicle, and is often painful, inefficient, and time consuming.

Optical-based methods, such as the use of laser light, have also been used for hair removal. U.S. Patent 4,388,924, for example, describes irradiation of individual hair follicles using a laser; in this method, heating of the hair's root section causes coagulation in local blood
15 vessels, resulting in destruction of the follicle and thus in removal of the hair. Related techniques, such as those described in U.S. Patent 5,226,907, involve destruction of the follicle by first applying a light-absorbing substance to the region of interest, the light-absorbing substance migrating at least part-way into the follicle, removing the excess light-absorbing substance, and then irradiating the region to heat the substance and thus the follicle to cause
20 destruction of the follicle.

The above prior art techniques suffer from a number of limitations. First, techniques for irradiating an individual hair follicle are time consuming and therefore are generally not practical for removing hairs other than from a very small region or from a region having few hairs situated therein. The procedure can also be painful, particularly if a needle-like element is inserted into
25 the hair follicle to facilitate light energy reaching the bulge and the root or papilla, parts of the hair follicle which must be destroyed in order to prevent regrowth of the hair. Where the irradiation source is not inserted into the follicle, it is difficult to get sufficient energy to the required portions of the follicle to result in destruction thereof without also causing significant damage to the surrounding tissue and thus causing pain and injury to the patient.

30 While the technique of the latter patent is advantageous in that it permits a number of hairs in a given region to be simultaneously removed, it is difficult with this technique to get the light-absorbing substance or chromophore deep enough into the follicle to effect destruction of the papilla. Further, this technique results in substantial energy being applied to and absorbed by

the epidermis and other skin layers in the region being treated, with significantly reduced energy reaching the root or papilla of the follicle. Total destruction of the follicle, and therefore permanent, or at least long term, hair removal is therefore difficult to achieve, particularly without risking damage to the epidermis and other layers of skin within the region.

5 A need therefore exists for an improved technique for performing hair removal which facilitates optical energy reaching the bulge and base, or root of hair follicles in a region while minimizing damage to the epidermis in the region, thereby minimizing patient discomfort and potential adverse side effects from the treatment.

10 Summary Of The Invention

In accordance with the above, this invention provides a method and apparatus for the simultaneous removal of a plurality of hairs from a skin region, each of which hairs is in a follicle extending into the skin from the skin surface. The technique involves placing an applicator in contact with the skin surface in the skin region and applying optical radiation of a
15 selected wavelength and of a selected flux through the applicator to the skin region for a predetermined time interval. The applicator is preferably pressed against the skin surface, thereby reducing the distance from the applicator to the papilla of the hair follicles and facilitating destruction thereof. Further, the invention also involves cooling the skin surface in the skin region to a selected depth during the applying of optical radiation to the skin region
20 and/or prior thereto. This allows the papilla of the hair follicles to be significantly heated without damage to the skin surface in the skin region up to the selected depth.

For preferred embodiments, the applicator is utilized to cool the skin surface in the skin region to the selected depth and the selected depth is preferably at least equal to the depth of the epidermis layer of the skin (i.e. the layer of the skin closest to the skin surface). The cooling by
25 the applicator may for example be accomplished by cooling at least the surface of the applicator in contact with the skin surface, such cooling preferably being accomplished both before and during the irradiation of the skin. For preferred embodiments, the cooling of the applicator is accomplished by passing a cooling fluid through the applicator. Further, it is also preferred that irradiation of the skin surface not be performed until the skin region has been cooled to
30 substantially the selected depth. For the most preferred embodiment, cooling is performed both before and during irradiation, and the selected flux and predetermined exposure time (i.e., time interval for irradiation) are selected such that there is at most minimal heating of skin in the skin

region to the selected depth, while there is sufficient heating of hairs and follicles below the selected depth to at least damage the hairs and follicles without causing significant damage to tissue surrounding the follicles. A preferred time interval for irradiation is 2 to 100 ms. The applicator is also preferably designed to converge optical radiation applied to the skin region, thereby further facilitating irradiation of the follicle papillas. For preferred embodiments, the applicator also has a convex surface in contact with the skin surface, applying substantially uniform pressure thereto to deform the underlying skin surface. For alternative embodiments, the applicator is designed to form a fold of the skin in the skin region and to apply optical radiation to two substantially opposite sides of the fold. For example, the applicator may have a slot formed in the surface thereof in contact with the skin surface, with at least a portion of the skin region being drawn up into the slot and optical radiation being applied to the skin region from at least two opposite sides of the slot.

It is also desirable that a substantial refractive index match be maintained between the applicator and the skin surface in said skin region. Such refractive index match may be provided by a layer of refractive index matching substance between the applicator and the skin surface in a skin region and/or by forming the applicator of a material which at least for the surface in contact with the skin region has a refractive index which substantially matches that of the skin surface.

To facilitate hair removal, hairs in the skin region may be shaved prior to irradiation. However, it may be preferable to epilate the hairs in the skin region before irradiation. When hairs are epilated, destruction of the follicles can be facilitated by filling the follicles from which the hairs have been epilated with a substance which preferentially absorbs optical radiation at the selected wavelength being used for irradiation (i.e. a chromophore). Further, where only temporary hair removal is desired, this may be accomplished for a period of up to several weeks, relatively painlessly, by applying the chromophore to the area, which has been preferably pre-shaved, which chromophore migrates into the hair follicles to a depth of a few millimeters, roughly to the depth of the sebaceous gland. Low level irradiation applied through the applicator to the skin region will then result in the destruction of the hair without destroying the follicle.

An applicator suitable for use in practicing hair removal in accordance with the above may include an inlet through which optical radiation is applied to the applicator, a surface shaped to contact the skin surface in the skin region, an optical path from the inlet to the surface, which path is substantially transparent to optical radiation at the selected wavelength, an element in the optical path for converging the optical radiation as it leaves the applicator through the surface

and some means for cooling the surface to a temperature below that of the skin region. As indicated previously, the surface is preferably formed of a material having a refractive index which substantially matches, but which is not less than, the refractive index of the skin surface in the skin region. For preferred embodiments, the element for converging the optical radiation is a lens and the means for cooling is a channel near the surface through which cooling water is passed. For one embodiment, the surface of the applicator in contact with the skin has a convex shape while for an alternative embodiment the surface has a slot formed therein, with the optical path leading to at least two opposite sides of the slot, and the applicator includes a means for drawing at least a portion of the skin region into the slot, this means for drawing preferably includes a vacuum applying element.

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention as illustrated in the accompanying drawings.

Brief Description Of The Drawings

Fig. 1 is a perspective view of a laser-based hair-removal device according to the invention;

Figs. 2A and 2B are cross-sectional views of an irradiating unit or applicator suitable for use with a hair-removal device of this invention, the applicator receiving, respectively, light from a fiber optic or fiber optic bundle, and from a mirror assembly;

Figs. 3A, 3B, and 3C are, respectively, an expanded, cross-sectional view of the contact device of the irradiating unit in direct contact with a hair-containing skin region, a cross-sectional, cut-out view showing the back-scattered optical fields at the contact device/epidermis interfacial region, and a cross-sectional cut-out view showing thermal transport at the interfacial region;

Fig. 4 is a plot showing the optical absorption spectra of melanin, hemoglobin, oxygenated hemoglobin, and water;

Figs. 5A and 5B show, respectively, the time and spatial profiles and the preferred optical field used during the hair-removal process;

Fig. 6 is a plot of the computer-generated optical intensity as a function of skin depth for different optical fields;

Fig. 7 is a photograph showing skin regions of a patient three months after being treated

according to the hair removal method of the invention;

Figs. 8A, 8B and 8C are oscilloscope traces showing, following irradiation, the time-dependent temperature responses of, respectively, dry black hair, wet black hair, and live skin surrounding the black hair sample;

5 Fig. 9 is a plot showing the temperature rise as a function of laser pulse energy for dry hair (DH), wet hair (WH), and skin (S) samples of eight different patients;

Fig. 10A is a partial cross-sectional view of the applicator of the invention being used to practice an alternative embodiment of the invention wherein epilation and filling of empty follicles with a chromophore are performed before irradiation; and

10 Fig. 10B is a cross-sectional view of an applicator for an alternative embodiment being used for hair removal.

Detailed Description

Referring to Fig. 1, an exemplary laser-based hair-removal system 10 includes a light
15 source 12, which may, for example, include one or more lasers for generating the irradiating field. The light source 12 may be optically coupled to a series of beam-manipulating optics 14 which, in turn, may be coupled via a fiber optic cable 16 (or other fiber optic device) to the irradiating unit or applicator 18. During the hair-removal therapy, the light source is powered by a voltage and current supply 19, and delivers a beam of light through the optics 14 and fiber
20 optics 16 to the irradiating unit or applicator 18. The field is then delivered to a region 20 of a patient 22 (positioned, for example, on a table 25, a chair, or other suitable positioning element depending on the location of the region 20 on the patient's body) resulting in hair removal from the region 20. Once the desired region is treated, the irradiating unit can be easily moved along the patient 22, as indicated by arrows 27, and used to treat subsequent regions.

25 The spatial and temporal properties of the optical field determine the efficacy of the hair-removal process, and some of these properties may, if desired, be adjusted using a series of controls 24, 26, 28 located on various components of the hair-removal system 10. For example, using controls 24 located on the power supply, the optical intensity and pulse repetition rate of the irradiating field can be controlled by adjusting parameters such as the voltage, current, and
30 switching rate for the laser's power supply. Other properties of the field, such as the wavelength and pulse duration, may be varied by controls 26 which adjust components (e.g., gratings, mirror or filter positions, shutters, or pulse-forming means) of the light source 12; however, for

preferred embodiments wavelength would not be adjusted. Similarly, controls 28 can be used to adjust the modulating optics 14, resulting in control of properties such as mode quality, beam diameter, and coupling of the irradiating field into the fiber optics 16. All controls may be adjusted by hand; and the system may also be operated (i.e. the laser turned on) by hand or,
5 alternatively, by using a foot pedal 30 connected to the system 10.

In alternate embodiments, the light source, coupling optics, and irradiation unit may be encompassed in a single, hand-held device. In this case, the light source is preferably an array of diode lasers coupled directly to the irradiating unit, and is powered by a small external power supply. The compact nature of this type of optical system allows for a more controllable,
10 maneuverable device, and additionally obviates the need for fiber optic delivery systems.

In order to effectively destroy the irradiated hair follicles without causing damage to the surrounding skin, the light field supplied by the system 10 and the irradiating unit 18 is designed to maximize the amount of light-induced heat deposited in the hair follicles, while reducing the degree of injury to the surrounding skin. It is preferred, for example, to deliver sufficient optical
15 energy to several "target" regions on the hair follicle; radiation delivered to these regions results in complete and localized destruction of the follicles.

Prior to treatment, the region to be treated may be shaved in order to facilitate irradiation of the follicles. Alternatively, as will be discussed later, hairs in the region may be epilated and a chromophore may be applied to region 20, which chromophore migrates into the empty follicles.
20 Excess chromophore may then be removed from the skin surface prior to irradiation. Prior to treatment, an anesthetic may also be injected locally or applied to the skin surface and following treatment, patients may be treated with topical antibiotic ointments.

Mechanical Structure

25 With reference now to Figs. 2A and 2B, the applicator or irradiating unit 18 of the hair-removal system allows delivery of the irradiating field 38 to hair follicles 40 located in the region 20. As shown in Fig. 2A, the field 38 may be delivered to the irradiating unit 18 using a fiber optic cable 16 (or other fiber optic device) containing one or more fibers or fiber optic bundles. In this case, after exiting the waveguide, the field 38 is typically spatially dispersed, and is
30 preferably collected and roughly collimated using a plano-convex lens 42. Alternatively, as shown in Fig. 2B, the field may be delivered to the irradiating unit using, for example, one or more reflecting mirrors 44. This allows the field 38 to be roughly collimated prior to impinging

on the lens 42. Depending on the focal length of the lens 42 and the mode quality of the irradiating field, the field is preferably condensed using, e.g., a plano-convex lens as shown in the figure. After passing through this optic, the beam then impinges on a lens or contact device 46 which is placed in contact with the skin region 20. The optical and mechanical properties of the contact device 46 are chosen to allow efficient coupling of the optical radiation into the skin region (resulting in a delivered field 38) and the thermal properties of the contact device are chosen to allow efficient coupling of heat from the skin region. Once delivered, the field is used to irradiate, heat, and then destroy the hair follicles 40. The contact device 46, in addition, is used to couple light and heat out of the superficial skin layer (i.e., epidermis) of the irradiated region. This allows the light-absorbing pigment (i.e., melanin) contained within the deep part of the hair follicles to be irradiated and selectively heated, permitting permanent destruction of the follicle, while potentially deleterious optical and thermal energy are simultaneously conducted out of the overlying skin layers. Thus, multiple hair follicles can be destroyed, permanently removing hair from the skin region without causing substantial pain or injury to the patient. The destroyed follicles are ultimately removed by the body.

Both the lens 42 and contact device 46 are preferably disposed in a housing 48 containing both entrance 50 and exit 52 ports for fluids such as cooling water and pure gas (i.e., nitrogen to prevent condensation on the lens) to flow into and out of; fluids may be used, for example, to cool the contact device 46, which, in turn, cools the skin surface. Alternatively, the housing 48 may include an electrically controlled cooler in order to provide accurate control over the temperature of the contact device 46. Preferably, when cooling means are used, the temperature of the surface layer or epidermis of the skin is reduced to between 4-15°C. In addition, in this case, it is preferred that a short time period (e.g., about 1 second) be allowed to elapse before irradiation in order to ensure that the epidermis is adequately cooled. An external casing 39, as indicated in Fig. 2B by the dashed line, or a fiber-coupling housing 37, as shown in Fig. 2A, may be used to connect the light-delivering means to the housing 48.

With reference now to Fig. 3A, the contact device 46 is preferably formed into a lens shaped in order to converge the irradiating field, preferably near the base of the hair follicles 40. In order to converge light, the contact device must be optically transparent at the irradiating wavelength, and preferably has a biconvex or plano-convex lens shape, preferably with an f number less than or equal to $f/1.0$, and a focal length of between about 0.5 and 2 cm. Control over the surface shape of the contact device allows the converged light field 38' to

simultaneously irradiate various target portions of the hair follicle, resulting in efficient destruction. Typically, each irradiated hair shaft has a diameter of about 75 microns, with the entire follicle having a diameter of about 200 microns. After passing through the contact device 46, the light field 38' is preferably converged through the epidermis 56 of the skin layer (having a thickness, e.g., of about 0.1 mm) and is condensed in the dermis 58 near the papillae 54 of the follicles 40. Because dermal thickness varies greatly over the body, the papillae may be superficial (as in, e.g., the eyelids and scrotum), but for most areas of interest (e.g., the face, axillae, and legs) the papillae are located at depths of approximately 4 to 7 mm beneath the epidermal surface. Located a few tenths of a millimeter below the papillae are neurovascular bundles 60 which serve the metabolic and other needs of a hair matrix, the region of rapidly growing keratinizing cells, located in the papilla, which produce the hair shaft 55. The matrix, papilla, and the corresponding vascular bundle, as well as the bulge near the center of the follicle, represent the follicular targets to be irradiated/destroyed. Preferably, during irradiation of these regions, the field is pulsed, the pulse duration of the irradiation being kept short enough so that damage is localized to a small region of dermis (typically within about 0.2 mm) surrounding each follicle in accordance with the principles of selective photothermolysis. The extent of damage is preferably much less than half the distance between neighboring follicles (typically between 1 and 4 mm); if it is significantly greater than this, the light-induced injury may result in a third-degree burn.

In addition to providing a light converging function, a contact device 46 having a convex-shaped surface 62 allows efficient compression of the skin during contact. Compression of the dermis 58 located near the surface 62 of the contact device decreases the distance between this region and the papillae; depending on the force applied, the distance may be decreased by up to several millimeters. Because the radiation field 38' is scattered and correspondingly attenuated during propagation through the dermis, compression of the skin results in bringing more light to the deep portions of the hair follicles for more efficient light-induced heating of the papilla. In addition, compression of the dermis by the contact device using a pressure greater than the patient's blood pressure forces light-absorbing blood out of the irradiated region (indicated during treatment by a whitening of the skin in the pressurized region). This reduces absorption of the optical field, resulting in more efficient delivery of light to the follicular target regions. Pressure applied using a contact device having a convex surface results in a relatively uniform displacement of blood from the skin region. A contact device having this shape is therefore

preferred to a flat device, which tends to produce regions having center portions which are not entirely blood-free.

In alternate embodiments, the contact device may be mounted in the housing in a spring-loaded fashion so that it may be forced against the skin surface with an adjustable pressure. In addition, in this embodiment, the spring mechanism may be attached to a sensor and readout
5 device so that the exact pressure applied to the skin surface can be accurately monitored and/or controlled.

When forced against the skin, the contact device 46 allows optical radiation to be coupled into and out of the epidermis. With reference now to Fig. 3B, the refractive index (n_{CD}) of the
10 contact device 46 should be approximately matched to that (n_{EP}) of the epidermis 56, which is approximately 1.55. Because light travelling from one refracting medium (i.e., the contact device) to another (the epidermis) is reflected at the interface 57 separating the two regions by an amount related to the square of the refractive index difference, nearly index-matching allows efficient coupling of the irradiating field into the skin. Thus, a contact device composed of a
15 material having a refractive index near 1.5 or somewhat greater allows the incident irradiating field to undergo minimal reflections (indicated in the figure by the arrow 64) at the epidermis/contact device interface 57. Similarly, as indicated in the figure by the arrows 66, optical fields within the dermis are back-scattered towards the epidermis due to diffuse reflectance. These back-scattered fields contribute to unwanted epidermal heating, and are easily
20 coupled out of the skin using the index-matched contact device 46. This allows minimization of the light-induced damage to the epidermis 56, while allowing effective irradiation of the follicle target sites within the dermis. In preferred embodiments, in order to be substantially index-matched, the contact device is preferably formed of a high-density material such as sapphire ($n_{CD} = 1.7$), fused silica ($n_{CD} = 1.5$), or similar optically transparent glasses or plastics. In order to
25 provide a convergent field entering the skin and to have the convex shape of the contact device as shown, it is advantageous to use sapphire, the slightly higher index of which facilitates the desired field convergence.

With reference now to Fig. 3C, in order to conduct heat away from the epidermis, it is additionally preferred that the contact device 46 be composed of a material having a high thermal
30 conductivity (k_{CD}) which is similar to that of the skin. This allows efficient transfer of heat (indicated in the figure by the arrows 68) from the epidermis 56, across the contact device/epidermis interface 57, and into the contact device 46. A high thermal conductivity, in

addition, is necessary to minimize local heating effects that may occur at the interface 57, thereby reducing the chance of thermally induced damage or injury to the irradiated epidermis. As will be discussed later, this is particularly important when the contact device is cooled. Ideally, the thermal properties of the contact device and the time the contact device is applied to the skin before irradiation begins allow minimization of heating near the epidermis, but have little effect on heat deposited near the papillae of the hair follicle (shown in the figure as region 70). Materials having high thermal conductivities include sapphire ($K_{CD} = 0.083 \text{ cal sec}^{-1} \text{ cm}^{-2} \text{ }^{\circ}\text{C cm}^{-1}$ along the C axis at 30°C), fused silica ($K_{CD} = 0.026 \text{ cal sec}^{-1} \text{ cm}^{-2} \text{ }^{\circ}\text{C cm}^{-1}$ along the C axis at 30°C), as well as other high-density glasses and plastics.

In addition, in order to improve both optical (i.e., transmission of back-scattered light) and thermal (i.e., heat conduction) properties at the contact device/epidermis interface 57, it is desirable to apply to the skin a topical liquid or emollient, such as a lotion, water, alcohol, or oil, having a refractive index which is similar to that of the contact device 46 and epidermis. For example, application of an oil having a refractive index between that of the epidermis ($n = 1.55$) and sapphire ($n = 1.7$) minimizes optical reflection effects at the interface, thereby allowing more efficient transfer of light into the skin region from the contact device and of back-scattered radiation from the skin region. Also, a liquid allows for more efficient transfer of heat by conduction from the skin into the sapphire, thereby reducing the degree of damage or injury to the epidermis.

Optical Properties

The temporal and spatial distribution of intensity for the irradiating optical field inside the skin ultimately determine the amount of heat deposited into the target regions of the hair follicle; these properties therefore can be selected and/or adjusted to optimize the hair-removal process. In particular, properties which affect the hair-removal process include the pulse energy, pulse duration, repetition rate (i.e., the time duration between subsequent pulses), wavelength, energy, exposure spot size, beam convergence as it enters the skin, and mode geometry (i.e., spatial extent and uniformity) of the optical pulse. These characteristics may be selected according to the pigment present in the hair and skin to be irradiated; preferably, each parameter is adjusted so that the temperature at each target site, immediately following irradiation, is elevated to between about 80 and 120°C . Heating the follicle to this temperature leads to permanent damage and subsequent removal.

Referring now to Fig. 4, the wavelength of the irradiating field is chosen to be resonant with the natural pigment (i.e., melanin) present in the target sites (i.e., the hair shaft, bulge, matrix, and papilla). The absorption spectra of melanin, water, hemoglobin, and oxyhemoglobin shown in the figure indicate the ability of these compounds to absorb optical radiation at different wavelengths; low absorption indicates that light at the particular wavelength will penetrate deeper in the absorbing media. In general, in order to selectively heat the target regions, the wavelength of the irradiating field is chosen to match the absorption spectrum of melanin, which basically absorbs light from about 200 to 1200 nm; conversely, the wavelength is mismatched to the absorption spectra of compounds contained in the skin, such as water and hemoglobin. Light having wavelengths between 680 and 1200 nm, a range indicated by the arrow 70 in the figure, is effectively absorbed by melanin while being relatively transmitted by both hemoglobin and water, and therefore can be used for selective heating of pigmented hair surrounded by white or lightly tanned skin. In particular, light in the range of 680 to 900 nm or 1000 to 1200 nm is preferred, as this radiation is strongly absorbed by melanin, and will not be absorbed by the bands present in water and in oxyhemoglobin near 950 nm. For patients with less melanin present in the hair follicles (e.g. with auburn or light brown hair), the shorter wavelengths in this region are preferable because of the higher absorption coefficient of melanin. In addition, other light-attenuating effects besides absorption, e.g., scattering of radiation, are also wavelength-dependent, and should be considered during selection of the optical field's wavelength. For example, in human skin, the penetration of light is partially determined by the transport scattering coefficient (μ_s), which decreases at longer wavelengths due to scattering in the dermis. For radiation at 1000 nm, μ_s is about 10 cm^{-1} ; light propagating into the skin from a generally index-matched medium at this wavelength will therefore reach a maximum intensity at about 1 mm below the skin surface.

Sources generating visible or near-infrared light in the preferred range of 680-1200 nm include diode ($\lambda \approx 800\text{-}1000 \text{ nm}$), Nd:YAG and Nd:YLF ($\lambda = 1064 \text{ and } 1053 \text{ nm}$), Ti:Sapphire and infra-red dye ($\lambda \approx 700\text{-}1000 \text{ nm}$), ruby ($\lambda = 694 \text{ nm}$) and alexandrite ($\lambda = 700 - 850 \text{ nm}$) lasers. Ruby, Nd:YAG and diode lasers (particular arrays of diode lasers) are preferred as these sources are commercially available, well-categorized, and can be manufactured on a small scale. Light sources of this type can be incorporated into compact hair-removal devices which, in turn, can be easily manipulated by the operator during hair-removal procedures.

The duration of the optical pulse can also be controlled in order to vary the heating of the

hair follicle. Referring now to Fig. 5A, the optical pulses, indicated by the waveforms 74, 74', preferably have durations 76, 76' which allow the follicle to be heated for short periods of time. The pulse width is controlled to vary the heat conduction during the optical pulse, and thus the damage of the follicle and its immediate surrounding dermis; too little damage results in hair re-
5 occurrence, while extensive damage may produce scarring in the irradiated region. Preferably, the pulse duration 76, 76' is between about 2 ms and 100 ms.

The exact pulse duration is dictated by the diffusion of heat in the skin, a process which roughly follows the heat diffusion equation relating the diffusion time t , diffusion distance d , and thermal diffusivity k , as discussed by in Welch, A.J. "The thermal response of laser-irradiated
10 tissue", IEEE J. Quant. Electron. QE-21 (12), 1471-1481 (1984): $t = d^2/4k$ (k for the human dermis is roughly $1.3 \times 10^{-3} \text{ cm}^2/\text{sec}$). The time needed for extraction of heat from the epidermis during a laser pulse is approximately 2 ms, and the thermal relaxation time for a typical 200 micrometer hair follicle is approximately 40 ms. For light exposures longer than a few hundred milliseconds, too much thermal diffusion may occur during the exposure period, resulting in
15 either inefficient destruction of the target regions of the hair follicle, excessive dermal damage, or both. Further, since most of the melanin (roughly two thirds) in the epidermis is in the lower portion of the epidermis, heating of the epidermis occurs primarily in the deeper portions thereof, and some time is required for this heat to reach the surface in order to be removed by the contact device 46. Therefore, since this time is at least 2 ms, this is the minimum suggested pulse
20 duration, with a longer time, preferably at least 5 ms, being suggested to minimize epidermal damage. Further, depending on the laser utilized, each pulse could be in the form of a single continuous pulse as shown in Fig. 5A or in the form of a train of closely spaced pulses of shorter duration, the space between such closely-spaced pulses being much shorter than 5 ms.

For a given fluence, the intensity of the optical field is inversely related to the pulse
25 duration; thus, when the pulse duration is below about $10\mu\text{s}$, large optical intensities may result in undesirable modes of damage to surrounding skin regions. In addition, short pulses may result in localized heat-induced "explosions" in the follicle which cause mechanical damage to the skin. In particularly preferred embodiments, the pulse has a duration or pulsewidth of about 2 - 100 ms. During this time period, thermal diffusion takes place over a distance of about 0.05 to 0.3
30 mm; damage confined to about this distance results primarily in destruction of the irradiated hair follicles, with little or no damage to the surrounding skin.

Optical pulses having well-defined and adjustable durations may be generated using

known techniques. For instance, intra-cavity modulation of the light field using electro or acousto-optic Q-switching devices allows generation of pulses having temporal profiles which are typically Gaussian in shape. Pulses made using these methods are typically too short, however, having durations in the sub-microsecond range. Normal-mode pulses produced by flashlamp excitation of ruby, alexandrite, Ti:sapphire, or Nd:YAG lasers are preferred because these typically are high-energy pulses in the 0.1 - 10 ms pulse duration region. Alternatively, a continuous (i.e., time-independent) optical field emitted by a laser can be externally modulated using, for example, a mechanical shutter or electro-optic gate. Modulation using external methods allows the pulse width to be easily varied from a few hundred microseconds to several hundred milliseconds. Pulses generated using external modulation may also have "square wave" temporal profiles (as shown in Fig. 5A) which allow a more uniform optical field to be applied to the region of interest. However, external modulation is not used for currently preferred embodiments.

When a contact device is used to deliver the optical pulse, a time delay preferably exists between the time at which the contact device contacts the skin surface and the arrival of the pulse. This allows the entire epidermal layer 56 to be cooled significantly prior to irradiation, thereby increasing its damage threshold. Pain and damage to the epidermis are thus reduced and are further minimized by continuing to cool contact device 46 during irradiation so that heat continues to be removed from the epidermis. However, heating at lower levels where destruction of the follicles, and in particular the bulge and papillae thereof, is desired is not affected by the cooling performed either before and/or during irradiation.

In addition, the time duration between optical pulses (indicated in Fig. 5A by the arrow 78) may be adjusted in order to control the total amount and rate on average of heat deposited into the irradiated region. If repetitive illumination is required for destruction of the follicle, this time period is preferably constant and lies between several seconds and a few hundred milliseconds. Alternatively, for "single shot" illumination, this time period is selectively controlled by the operator. In this case, a single laser shot is delivered to the region of interest, and then the region is inspected by the operator for damage. If more radiation is required, additional laser shots can then be delivered to the region. Otherwise, the irradiation unit is translated and used to treat a separate region.

The spatial extent of the optical field is chosen to allow multiple hair follicles to be irradiated with a single laser shot. In addition, larger spot sizes are preferred because attenuation

along the beam axis within skin due to scattering decreases as the beam radius, R , increases. Thus, wide-area beams allow more efficient delivery of optical radiation to the deep target sites. Referring now to Fig. 5B, the width 80 of the spatial profile 82 of the irradiating beam at the surface of the skin is preferably on the order of, and preferably much greater than, the depth of the target to be irradiated. Most preferably, the beam diameter is at least 8 mm. The area of the irradiating field is preferably between about 0.5 and 2 cm², and is most preferably between 0.75 and 1 cm². Because the beam is preferably converged, the spatial profile will be condensed as a function of depth before reaching a waist at a depth defined by optical scattering in the dermis. Preferably, as shown in Fig. 5B, the intensity across the beam diameter is roughly constant in order to provide a substantially uniform irradiating field.

Referring now to Fig. 6, following illumination, the intensity distribution of optical radiation (i.e., the y axis in the figure) as a function of skin depth (i.e., the x axis) is calculated using Monte Carlo-based computer simulations. The distribution is a function of the beam's spatial profile, the optical properties of the medium in contact with the skin. Although the plotted data is based on a computer simulation, and is thus only an approximate, the x axis units are estimated to be about 500 microns per tick mark. The first curve 90 shows the skin depth-dependent properties of an optical field originating from a small, collimated spot of 800 nm light in air. In this case, the majority of the optical intensity is distributed near the surface of the skin (indicated by the "0" point along the x axis), with the intensity dropping off rapidly at larger depths. A larger, collimated spot originating from air (curve 92) has a more evenly distributed skin depth-dependent intensity, although the majority of the light is still concentrated near the skin surface. Delivering a large, collimated radiation spot from a material having a refractive index of 1.5 (curve 94) results in a relatively uniform optical intensity in the first millimeter or so of the skin; at larger depths, this intensity starts to tail off with a relatively slow time constant. Finally, in the preferred embodiment, a large, spatially converging optical field from the $n = 1.5$ refracting material has an intensity at the skin surface which increases to a maximum after propagating about a millimeter into the skin. The intensity then attenuates as a function of skin depth with a time constant slower than that exhibited by the curve 94. Thus, a field of this type can be used to effectively heat the target sites of the follicle, with reduced heating of the skin at the surface, thus reducing heat injury to the skin.

In the case where the illuminating laser generates a beam having a diameter less than the preferred values, it may be necessary to expand the beam prior to delivery to the irradiating unit.

This may be done with conventional telescoping optics, e.g., two-lens systems configured to first expand and then collimate the emitted beam. Alternatively, as shown in Fig. 2A, the irradiating field may be coupled into an optical fiber and then delivered to the irradiating unit. In this case, the emerging field is naturally dispersed due to the waveguide nature of the fiber, and is then collected by a collimating lens. Displacement of the lens from the fiber tip allows the irradiating beam's profile to be increased to the desired amount.

The fluence of the optical field will be varied according to the degree of pigmentation in the patient, and is preferably between about 10 and 200 J/cm² for each pulse; patients with darker hair will require lower fluence than patients with lighter hair. Most preferably, the pulse fluence of the irradiating field for pulses of about 1 ms duration is between 30 and 50 J/cm². As described herein, in all cases, the fluence is adjusted in order to heat the target regions to the desired temperature of approximately 80 to 120°C. Moreover, the level of fluence may be increased as the pulse duration is increased in order to compensate for less efficient heating of follicles due to heat conduction during long pulses. It may be necessary to increase or decrease the optical fluence in order to heat the hair follicle to the desired temperature if the wavelength of the irradiating light field does not lie in the preferred spectral regions (i.e., 680-900 nm or 1000-1200 nm). In addition, in cases where the laser output is below the desired optical fluence, it may be necessary to amplify the individual pulses prior to irradiating the skin. Optical amplifiers, such as external optical cavities, may be used for this purpose.

Table 1, shown below, lists the preferred parameters of the optical fields used for hair removal. The value of each parameter depends on the amount of hair in the region of interest, the degree of pigmentation of the hairs, and the pigmentation of the surrounding skin of the patient.

Table 1 - Preferred Optical Field Parameters

<u>Parameter</u>	<u>Range</u>	<u>Preferred Values</u>
Wavelength	680 - 1200 nm	680-900, 1000-1200 nm
Pulse Duration	50 μ s - 200 ms	2 - 100 ms
Beam Area	> 0.5 cm ²	0.75 - 1.0 cm ²
Pulse Energy	10 - 200 J/cm ²	30 - 50 J/cm ²
Optical Coupling	external $n \geq 1.4$	$n = 1.5$ to 1.7

Beam Convergence, At Skin Surface	collimated or convergent	f# 0.5 - 2
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The inventions will now be further described with reference to the following examples.

5 **Examples**

In order to demonstrate the efficacy of the hair-removal device according to the invention, *in vitro* black-haired dog skin was exposed to light from the normal mode of a ruby laser at $\lambda = 694$ nm with a pulse duration of 270 μ s and optical fluences of 40 J/cm², 71 J/cm², and 160 J/cm².

- 10 The spatial extent of the beam (8 mm diameter at the skin surface) allowed irradiation of approximately 100 hairs with a single laser shot. Following irradiation, each skin region was examined histologically. Examination revealed that at the highest fluences, dermal damage consistent with scarring of the skin was evident, indicating that at the highest fluences, light-induced thermal damage was not selective to the hairs. In contrast, at the lower fluences, and
15 particularly at 40 J/cm², localized follicular damage was observed, with no noticeable damage occurring in the neighboring skin regions or dermis between hair follicles.

In a separate set of experiments, in order to show that the temperature increase within the irradiated hair is dependent on the degree of pigmentation, fresh human hair and skin samples having different colors were exposed using the hair-removal method described herein. The light
20 source for all experiments was the ruby laser described above. Emitted light was first coupled into an enclosed beam-steering device containing several mirrors coated to have high reflectivities at 694 nm, and then delivered to an irradiating unit similar to that shown in Fig. 2B. The unit included a 5-cm plano-convex glass lens positioned at the proximal end of a water-cooled plexiglass housing. A sapphire contact device shaped as a 1-cm focal length lens was
25 disposed at the distal end of the contact device, with the convex side touching the skin to allow compression during exposure as described above. Human skin was irradiated with an 8 mm diameter beam by pressing the cooled (4°C) contact device against the skin region of the patients, and then delivering a single laser shot. Each shot typically resulted in the simultaneous exposure of about 10 hairs.

- 30 The skin and hair of six adult patients having hair color ranging from red to black was irradiated and then observed. In each patient, eight treatment sites, each having an area of 10

cm², were irradiated. In order to monitor destruction of the papilla, sites 1-4 were wax-epilated prior to exposure to laser light, while sites 5-8 were shaven prior to exposure. Each site then received an optical fluence of either 28 J/cm², 42 J/cm², or 57 J/cm². Patients were seen in follow-up examinations one month and three months (and for some patients also one year) after exposure. As seen from the photographs of the exposed regions shown in Fig. 7 (i.e., regions A-C), hair regrowth after three months was minimal or non-existing in all cases compared to the shaved-but-untreated region (Region D), clearly indicating permanent damage to the hair follicle. In the figure, sites A-C were treated with decreasing energy from the laser. It is clearly evident that hair removal is relatively less pronounced in region C, treated with a fluence of 27 J/cm². Region D, the control region, was shaven at the same day regions A-C were treated. In addition, histological specimens obtained from the treated sites revealed that damage occurred exclusively to the hair follicle, while the surrounding dermis was essentially spared. There was statistically significant loss of hair for all of the subjects in the laser-treated sites compared with unexposed, shaven control sites. At one year later, there was also significant permanent hair loss without any scarring.

A separate set of experiments permitting measurement of the time-dependent temperature characteristics of hair and skin samples were conducted using a pulsed photothermal radiometry (PPTR) apparatus. In these experiments, the ruby laser described above was used at lower fluences to provide optical pulses having an energy allowing heating, but not destruction, of the follicles. Output from the laser was focussed onto the samples of human hair and skin to provide a uniform excitation field. A New England Research, Inc. black-body radiation detector containing an amplified, liquid nitrogen-cooled HgCdTe detector was used to monitor time-dependent characteristics of the sample temperature, and a Gentec, Inc. laser energy meter was used to monitor the irradiating pulse. The output from both detectors was then amplified with a compensated 0-10 Mhz dc-coupled preamplifier, and then relayed to a digital oscilloscope for recording and storing the data.

Eight patients having various skin types and hair coloring ranging from red/blonde to black were studied. In general, the PPTR results indicated that following irradiation at 694 nm, black hair experienced a larger temperature rise than lighter brown hair, and that both of these specimens experienced higher temperature rises compared to red/blonde hair. In addition, following irradiation, type II skin had a lower temperature rise than type III or type IV skin.

Referring now to Figs. 8A-8C, in a particular example using a patient with black hair and

white skin, time-dependent traces measured using the PPTR apparatus indicate that 400 ms after irradiation, both wet and dry black hair experience, respectively, temperature rises of about 7°C and 72°C (Figs. 8A and 8B) from a baseline temperature of 23°C, whereas the surrounding skin (Fig. 8C) undergoes a temperature rise of less than 1°C. The difference in the temperature rise and time-dependent decay characteristics of the wet hair is likely due thermal effects (e.g., the higher heat capacity of wet hair).

Referring now to Fig. 9, in all cases, the normalized temperature rises (i.e, the ratio of temperature rise to laser pulse energy) in the wet and dry hair follicles were significantly higher than those measured in the skin, indicating selective heating of the follicles using the method of the invention. Table 2, shown below, lists the hair and skin types of each patient in the study. The patient numbers in the table correspond to the patient numbers in Fig. 9.

Table 2 - Patient Hair and Skin Types

<u>Patient</u>	<u>Hair</u>	<u>Skin Type</u>
1	Red	II
2	Brown	III
3	Brown	II
4	Gray/Black	III
5	Gray/Black	III
6	Dark Brown	III
7	Gray/Black	II
8	Black	III

Other Embodiments

Fig. 10A illustrates an alternative embodiment of the invention wherein the region 20 is epilated rather than being merely shaved prior to treatment in accordance with the teachings of this invention. A fluid solution or suspension 100 containing a chromophore may then be applied to the skin region 20, with the chromophore containing fluid migrating into the empty follicles and filling the follicles. "Capillary action" of the fluid/chromophore into the follicles is desirable and may be enhanced by providing a low surface tension between the fluid and skin, for example by using surfactants or solvents. The excess fluid/chromophore may then be removed from the skin surface by washing, wiping or stripping. During irradiation, the chromophore 100 in the follicle absorbs light and is heated and, along with the heating of the

melanin of the follicle itself, results in significant heating of the follicle to destroy the portions thereof, including the bulge and the papilla, required to prevent regrowth of hair. The chromophore therefore must absorb light at the wavelength or wavelengths used for irradiation. Suitable chromophores might include a carbon particle suspension or a dye such as methylene blue or indocyanine green. Melanin itself in liposomal form might also be used. Since the chromophore is only in the follicles, this technique maximizes damage to the follicles while minimizing damage to surrounding tissue, and for this reason is a preferred way of practicing the invention, especially for those with blond, red, light brown or other light colored hair. Except for the differences indicated above, this embodiment of the invention operates in the same manner described for earlier embodiments, including the cooling of contact device 46, the deformation of the skin in the region 20, and the preferred optical irradiation, with the exception that lower frequency may be allowed when using the chromophores.

Fig. 10B illustrates another alternative embodiment of the invention wherein the contact device or applicator 46' is modified so as to simultaneously expose both sides of a skin fold.

This further increases the relative delivery of light to the deep portion of the follicles. In Fig. 10B, the contact device has for example an opening or slot 110 in the face of the applicator into which the area 20 of the skin may be drawn by for example vacuum or suction being applied to line 112 leading into the top of slot 110, the skin in slot 110 being formed into a fold 113. Radiation may be applied through a fiber-optic bundle 114 which divides to apply the radiation to lenses 116 on either side of slot 110. Cooling water may be flowed over the surfaces of lenses 116 through a line 118. Alternatively, two applicators similar to those shown for example in Fig. 2A or 2B can be positioned on opposite sides of a skin fold formed by clamping the skin region therebetween or by other suitable means.

The advantage of folding the skin as discussed for the above embodiments is that radiation is applied to a relatively thin section of skin from both sides. Thus, the papilla of a given follicle may be receiving radiation not only from the lens 116 on the side of slot 110 where the follicle is located, but also some radiation from the lens 116 on the opposite sides of the slot. Thus, energy applied to the papilla of each follicle is increased without increasing the energy at the surface, thus facilitating hair removal with less pain and injury. By making the slot 110 relatively narrow, pressure is applied to the skin on both sides of the slot, the skin being compressed between the walls of the slot. The advantages of compressing the skin, including removing blood therefrom and reducing the distance from the skin surface to the papilla, are thus

also achieved by this embodiment of the invention. Clamping to form the fold would also apply pressure to the skin.

It may also be possible to utilize the teachings of this invention for short term hair removal, the device serving as for example a razor which might provide a shave lasting for perhaps one to two weeks. This is achieved by applying the fluid/chromophore to the region which is to be "shaved" which region has preferably been shaved using conventional techniques, but not epilated. In this case the chromophore can only migrate a few millimeters into the follicle, to for example the level of the sebaceous gland. Excess chromophore may then be removed, and the contact device of this invention utilized with relatively low level radiation to heat the chromophore, and destroy the hair surrounded thereby, without substantial damage to either the skin or follicle.

Further, while cooling water has been shown for the preferred embodiment to cool contact device 46, this is not a limitation on the invention and other cooling techniques may be utilized. For example, a low temperature gas or liquid gas may be passed over the contact device for cooling purposes or the contact device may be sufficiently cooled prior to use so that it can continue to perform the cooling function during irradiation without having a cooling medium passed thereover. Other cooling techniques known in the art may also be utilized.

Other embodiments are within the scope of the following claims. For example, the contact device may not be cooled or cooling of the epidermis may be performed without an applicator (for example cryogenically). Where an applicator is not utilized, radiation is applied directly to the region of interest after passing through the appropriate optics.

Thus, while the invention has been particularly shown and described above with reference to preferred embodiments, the foregoing and other changes in form and detail may be made therein by one skilled in the art without departing from the spirit and scope of the invention.

CLAIMS

1. A method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising the steps of:
 - 5 (a) placing an applicator in contact with the skin surface in said skin region; and
 - (b) applying optical radiation of a selected wavelength and of a selected fluence through said applicator to said skin region, said applying step lasting for a predetermined time interval.
- 10 2. A method as claimed in claim 1 including the step of (c) utilizing said applicator to cool the skin surface in said skin region to a selected depth.
3. A method as claimed in claim 2 wherein the skin has an epidermis layer which is the layer of the skin closest to said skin surface, and wherein said selected depth is substantially the
15 depth of said epidermis layer.
4. A method as claimed in claim 2 wherein step (c) includes the step of (d) cooling at least the surface of said applicator in contact with said skin surface both during step (b) and prior to the performance thereof.
20
5. A method as claimed in claim 4 wherein step (d) is performed by passing a cooling fluid through said applicator.
6. A method as claimed in claim 4 wherein step (b) is not performed until the skin surface in
25 said skin region has been cooled to substantially said selected depth.
7. A method as claimed in claim 2 wherein step (c) is performed during step (b), and wherein said selected fluence and said predetermined time interval are selected such that there is at most minimal heating of skin in said skin region to said selected depth, while causing
30 sufficient heating of at least one of hairs and follicles below said selected depth to at least damage said hairs and follicles without causing significant damage to tissue surrounding said follicles.

8. A method as claimed in claim 7 wherein said selected fluence and said predetermined time interval are such as to result in the substantial destruction of said follicles.
9. A method as claimed in claim 7 wherein said selected time interval is 2 to 100 ms.
- 5 10. A method as claimed in claim 1 wherein step (b) includes the step performed by the applicator of converging the optical radiation applied to said skin region.
11. A method as claimed in claim 1 wherein during steps (a) and (b) pressure is applied to the
10 applicator so as to cause the applicator to deform the skin region thereunder.
12. A method as claimed in claim 11 wherein the applicator has a convex surface in contact with the skin surface.
- 15 13. A method as claimed in claim 1 wherein step (a) includes the step of forming a fold of the skin in said skin region, and wherein, during step (b), optical radiation is applied to two substantially opposite sides of said fold.
14. A method as claimed in claim 13 wherein the applicator has a slot formed in the surface
20 thereof in contact with the skin surface, wherein during step (a) at least a portion of the skin region is drawn up into said slot, and wherein during step (b) optical radiation is applied to the skin region from at least two opposite sides of said slot.
15. A method as claimed in claim 1 wherein step (a) includes the step of (e) providing a
25 substantial refractive index match between the applicator and the skin surface in said skin region.
16. A method as claimed in claim 15 wherein step (e) includes the step of providing a layer of a refractive index matching substance between the applicator and the skin surface in said skin region.
- 30 17. A method as claimed in claim 1 including the step performed before step (a) of shaving the hairs in said skin region.

18. A method as claimed in claim 1 including the step performed before step (a) of epilating the hairs in said skin region.

19. A method as claimed in claim 18 including the step performed after the epilating step but before step (a) of filling the follicles from which the hairs have been epilated with a substance which preferentially absorbs optical radiation at said selected wavelength.

20. A method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising the steps of:

(a) applying optical radiation of a selected wavelength and of a selected fluence to said skin region, said applying step lasting for a predetermined time interval; and

(b) cooling the skin surface in said skin region to a selected depth during at least one of step (a) and prior step (a);

whereby at least one of the hairs and follicles may be heated and damaged without causing significant damage to the skin surface in said skin region up to said selected depth.

21. A method as claimed in claim 20 wherein step (b) is also performed before the performance of step (a) to precool the skin surface in said skin region to substantially said selected depth.

22. A method as claimed in claim 20 wherein step (b) is performed during step (a), and wherein said selected fluence and said predetermined time interval are selected such that there is at most minimal heating of skin in said skin region to said selected depth, while causing sufficient heating of at least one of hairs and follicles below said selected depth to at least damage said hairs and follicles without causing significant damage to tissue surrounding said follicles.

23. An applicator suitable for use in practicing the method of claim 1 comprising:
an inlet through which optical radiation is applied to the applicator;
a surface shaped to contact the skin surface in said skin region;
an optical path from said inlet to said surface which path is substantially transparent to

optical radiation at said selected wavelength;

an element in said optical path for converging the optical radiation as it leaves the applicator through said surface; and

means for cooling said surface to a temperature below that of the skin region.

5

24. An applicator as claimed in claim 23 wherein at least said surface is formed of a material having a refractive index which substantially matches, but which is not less than, the refractive index of the skin surface in said skin region.

10 25. An applicator as claimed in claim 23 wherein said element is a lens.

26. An applicator as claimed in claim 23 wherein said means for cooling is a channel near said surface through which cooling water is passed.

15 27. An applicator as claimed in claim 23 wherein said surface has a convex shape.

28. An applicator as claimed in claim 23 wherein said surface has a slot formed therein, wherein said optical path leads to at least two opposite sides of said slot, and including means for drawing at least a portion of said skin region into said slot.

20

29. An applicator as claimed in claim 28 wherein said means for drawing includes means for applying vacuum to said slot.

30. Apparatus for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the apparatus comprising:
25 an applicator which is adapted to be in contact with the skin surface in said skin region;
a source of optical radiation of a selected wavelength, selected fluence and selected duration; and

means for applying the optical radiation from said source to said applicator, the optical
30 radiation being passed through the applicator to said skin region.

31. Apparatus as claimed in claim 30 wherein said applicator has a surface in contact with the

-25-

skin surface, and including means for cooling said surface of the applicator below that of the skin region.

32. Apparatus as claimed in claim 31 wherein said means for cooling is a channel near said
5 surface through which cooling water is passed.

33. Apparatus as claimed in claim 31 wherein said source of optical radiation is a laser, and
wherein said selected duration is 2 to 100 ms.

1/8

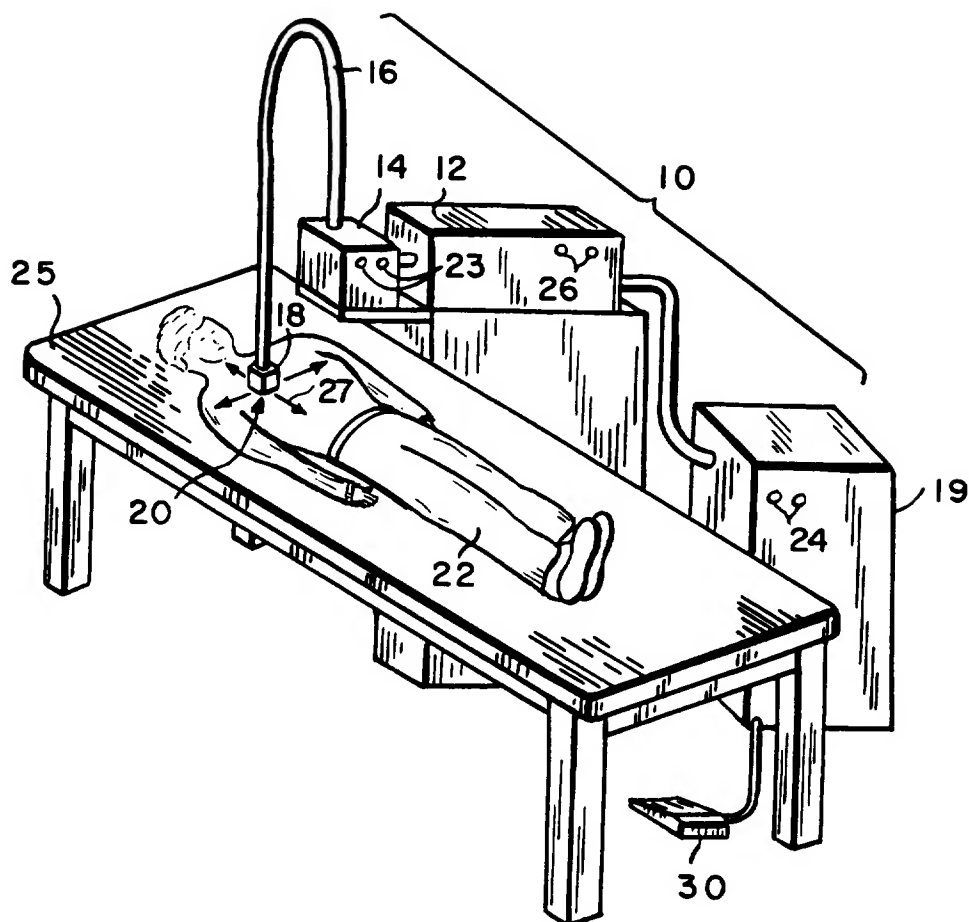


FIG. 1

2 / 8

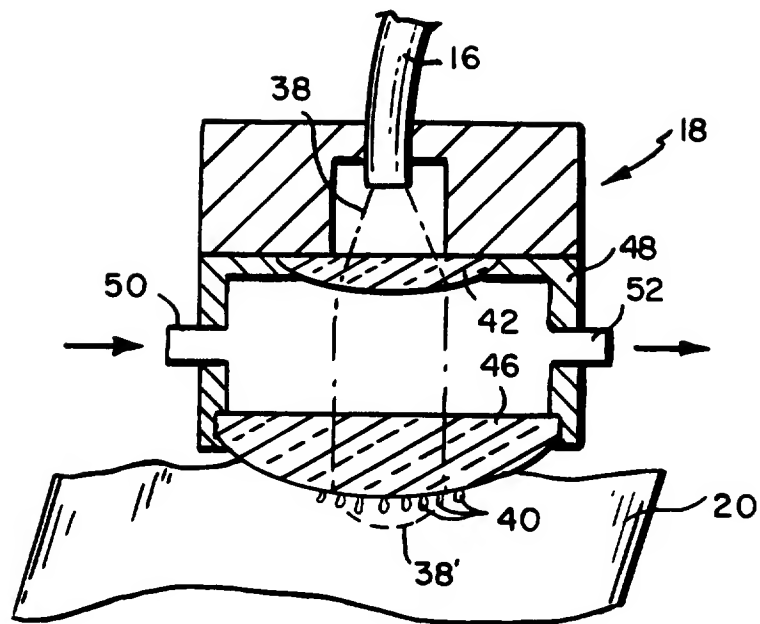


FIG. 2A

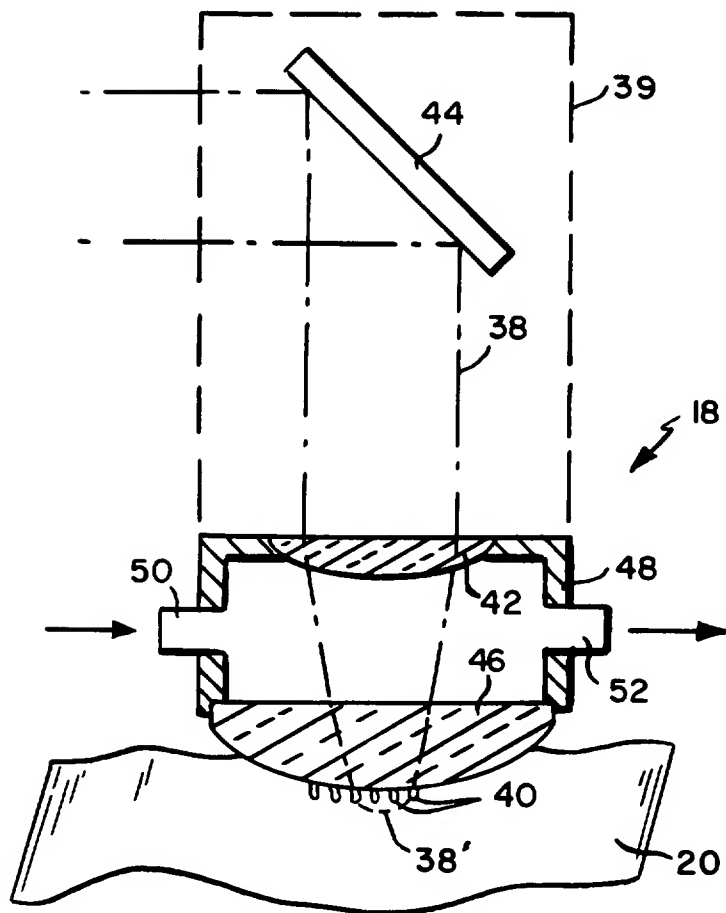


FIG. 2B

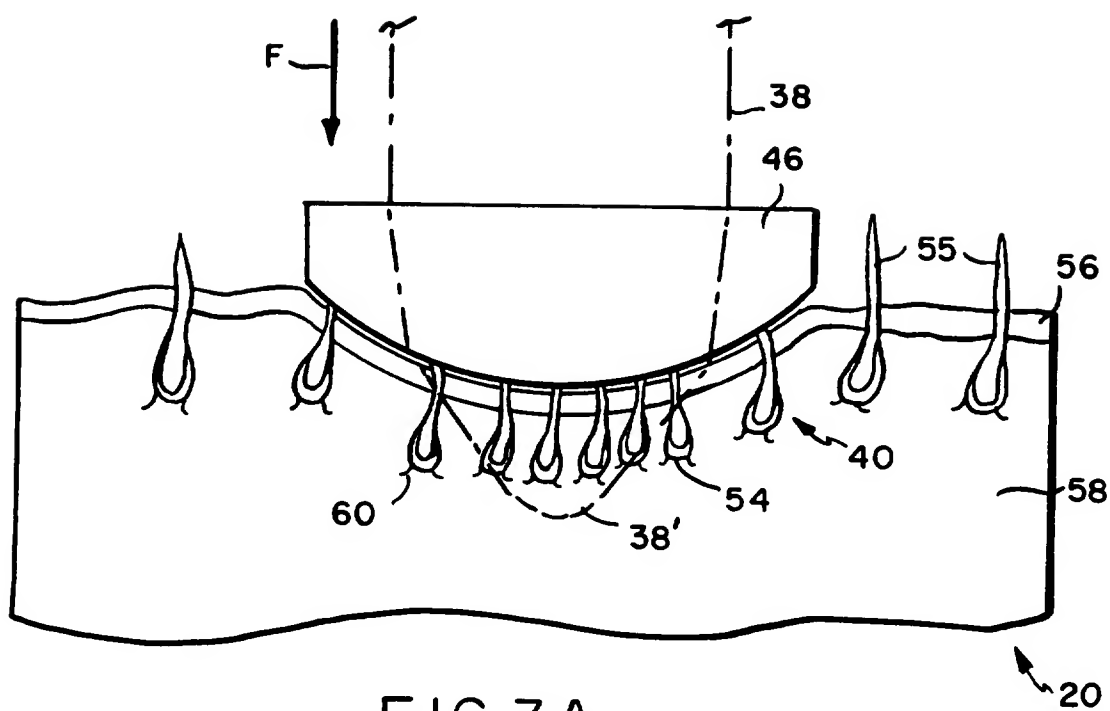


FIG. 3A

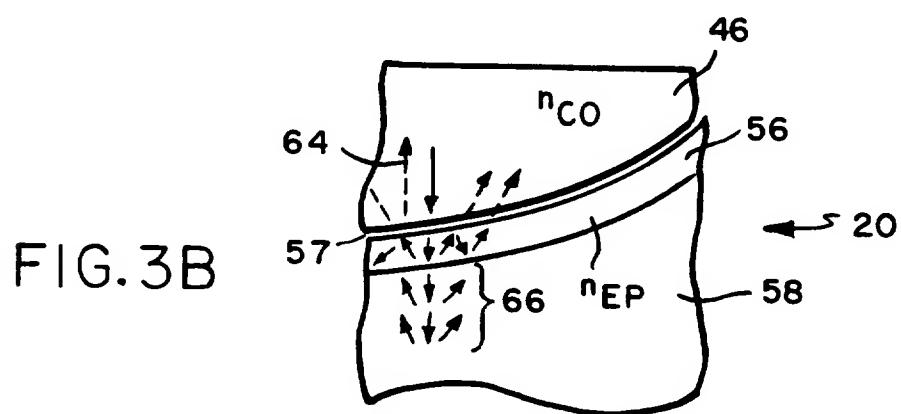


FIG. 3B

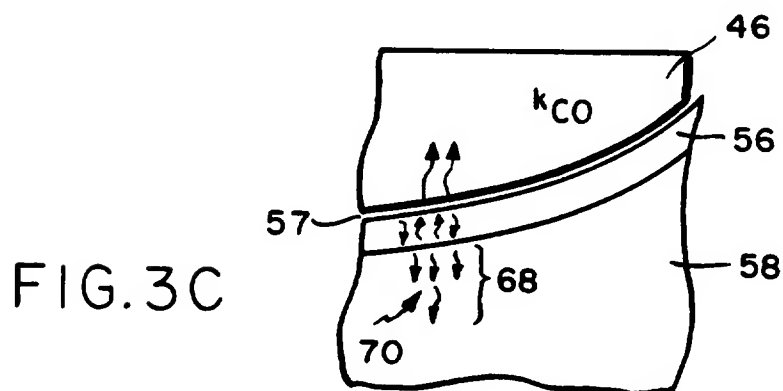


FIG. 3C

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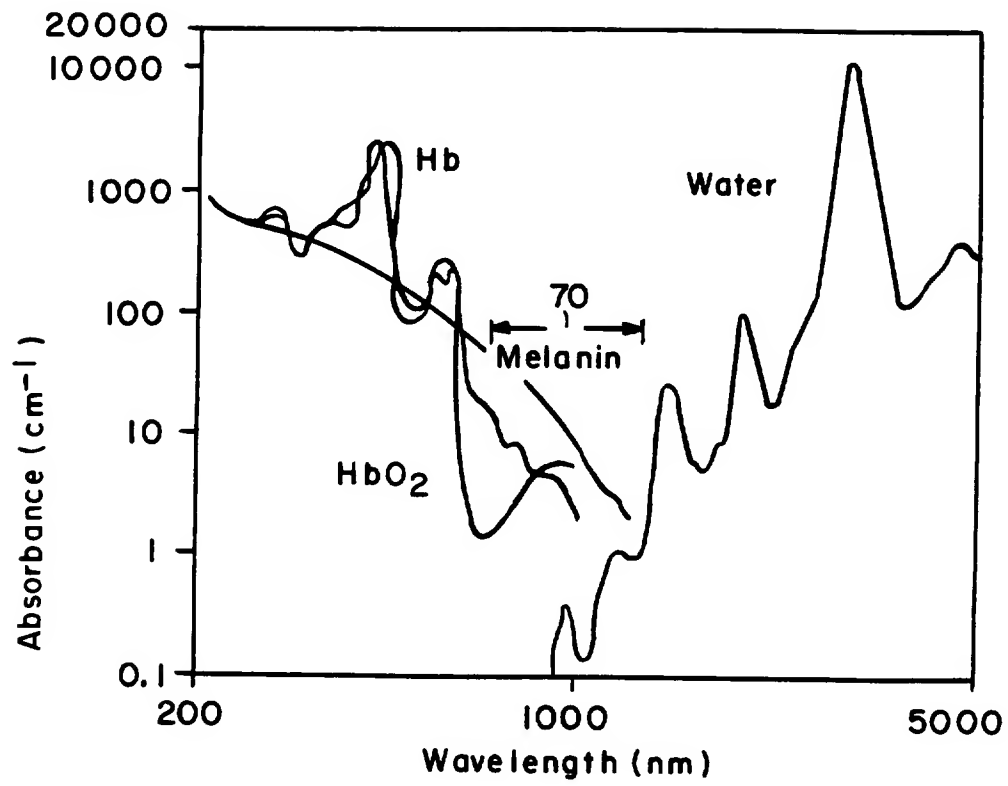


FIG. 4

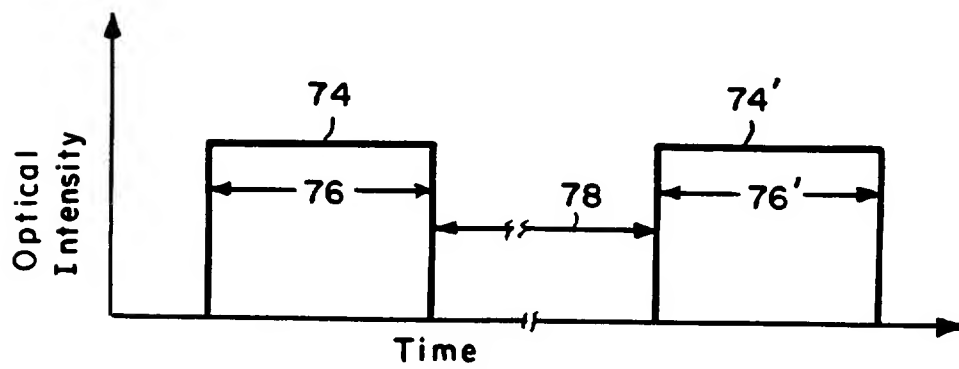


FIG. 5A

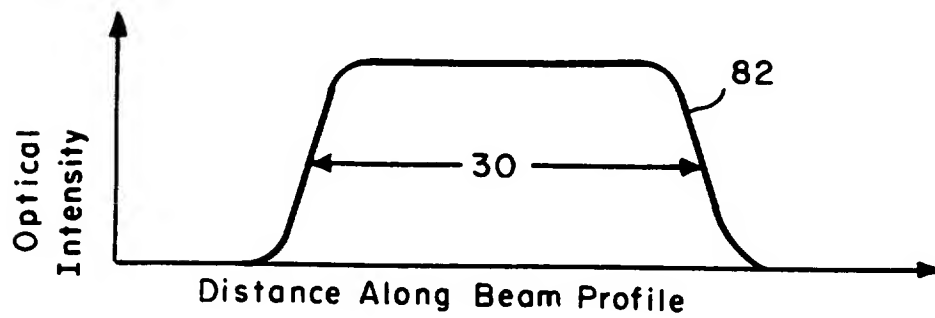


FIG. 5B

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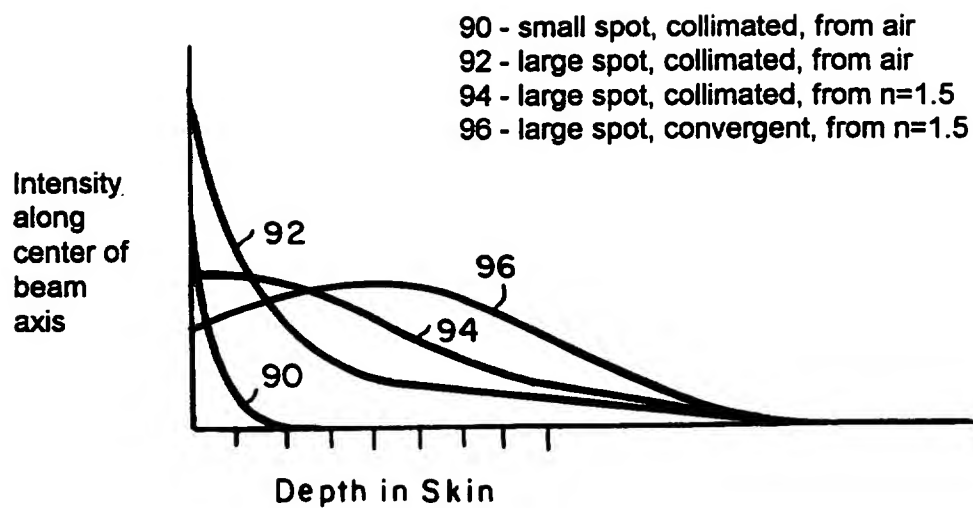


FIG. 6

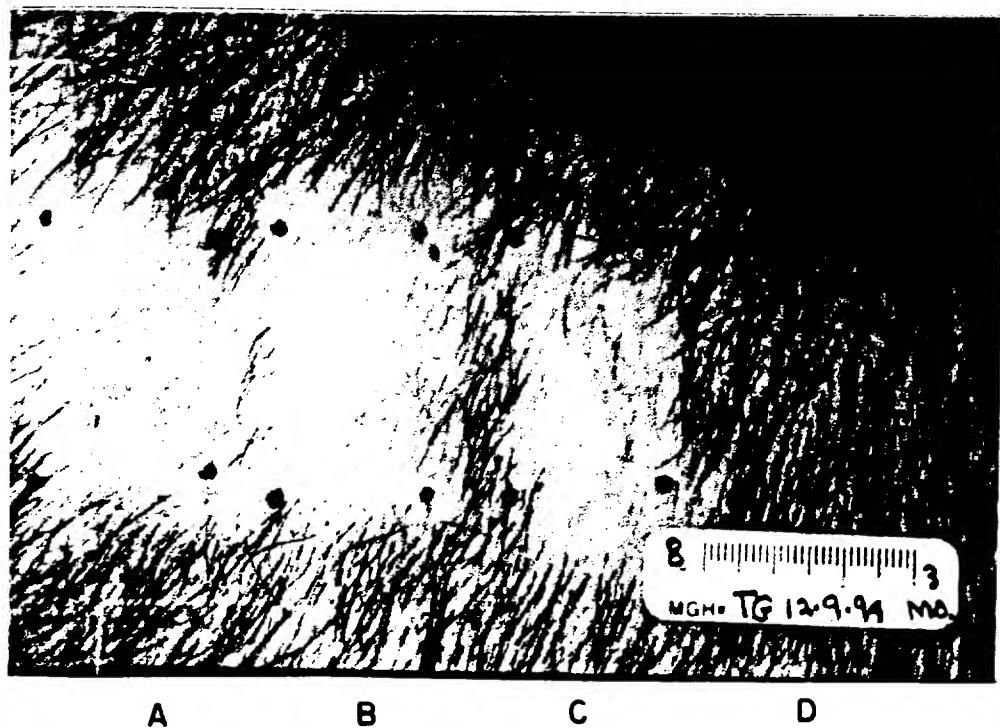
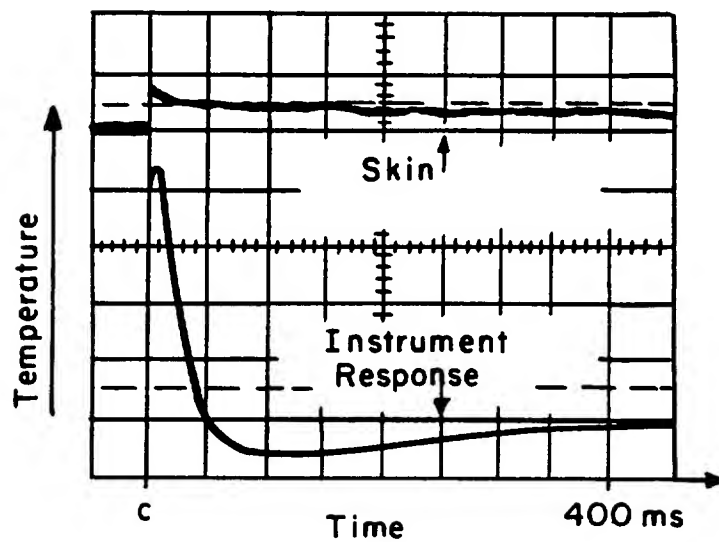
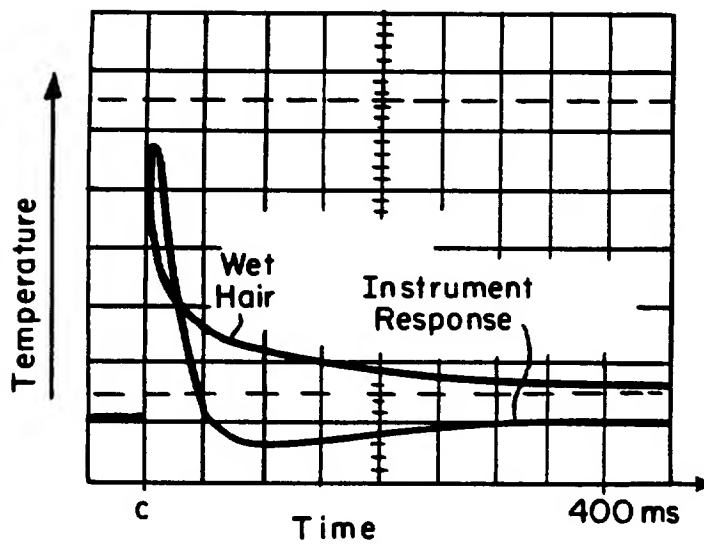
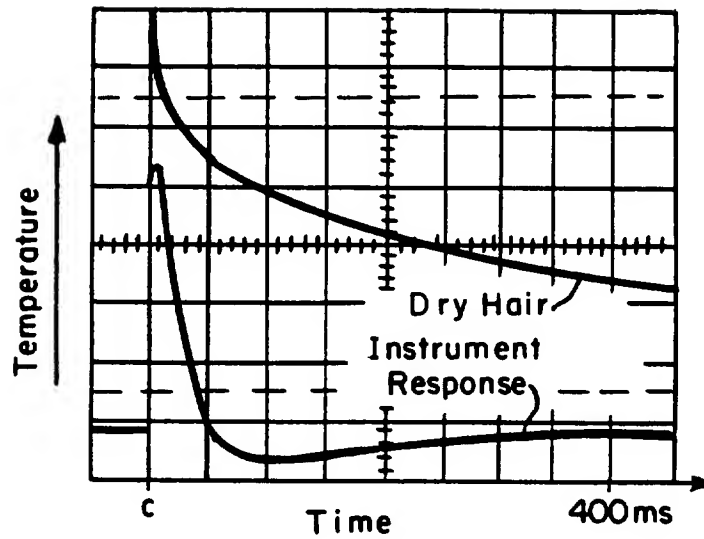


FIG. 7

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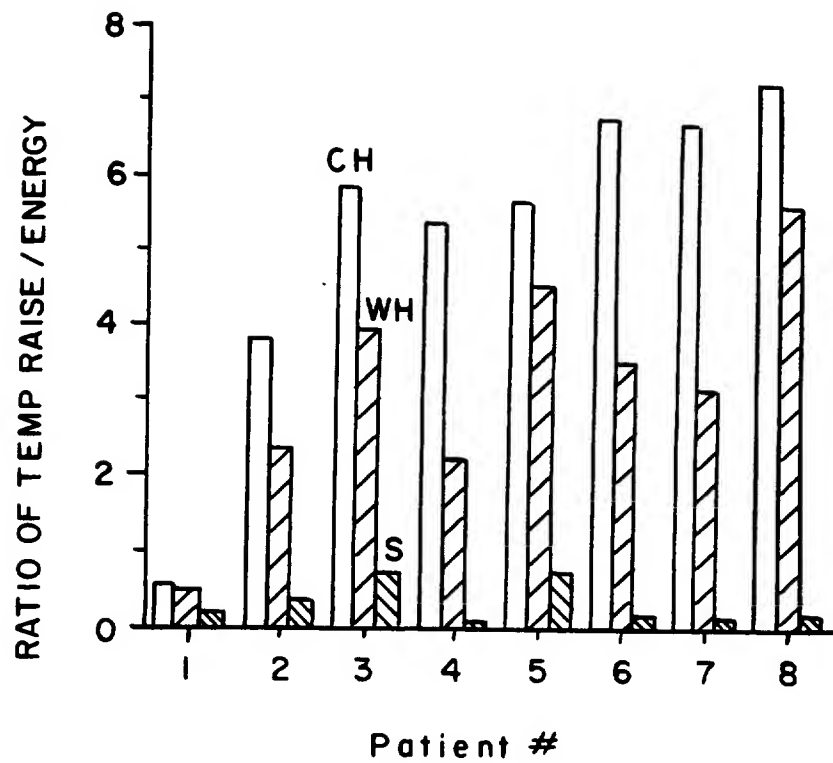


FIG. 9

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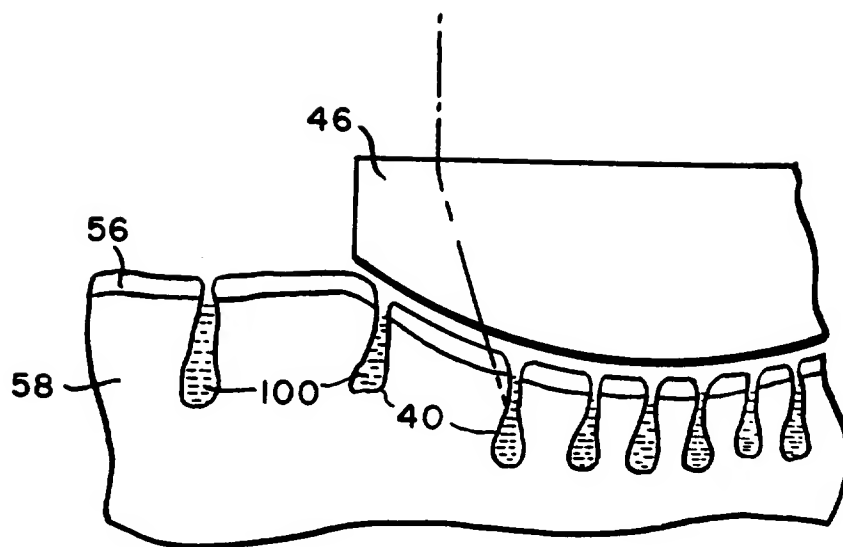


FIG. 10A

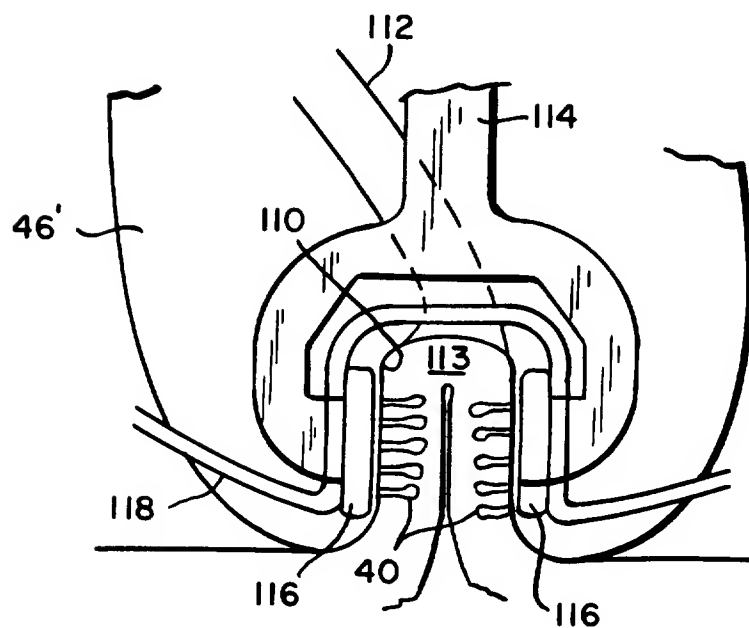


FIG. 10B

INTERNATIONAL SEARCH REPORT

Int. .onal Application No

PCT/US 96/01235

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/36 A61B17/41

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61N A45D B26B A22B A22C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP,A,0 142 671 (BLOCK) 29 May 1985 see claim 1	1,30 2-12, 15-29, 31-33
Y	--- US,A,5 057 104 (CHESS) 15 October 1991	2-9, 20-23
Y	see column 3, line 65 - column 4, line 2 see column 4, line 51 - line 56	26,31-33
Y	--- GB,A,2 123 287 (SUTTON) 1 February 1984	10-12, 15-19, 24,25
Y	see figure 1	27
Y	--- FR,A,2 591 902 (COLLIN) 26 June 1987 see page 6, line 2 - line 11 --- -/--	28,29

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

11 June 1996

Date of mailing of the international search report

20.06.96

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Glas, J

INTERNATIONAL SEARCH REPORT

Int. Patent Application No.

PCT/US 96/01235

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,93 05920 (KOZILOWSKI) 1 April 1993 see column 6, line 33 - column 7, line 5; figure 2 ---	14
A	US,A,5 226 907 (TANKOVICH) 13 July 1993 cited in the application see claim 1 ---	1,19
A	WO,A,92 16338 (KELMAN) 1 October 1992 see page 6, line 24 - page 7, line 3 -----	1,29

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. .ional Application No

PCT/US 96/01235

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		CA-A- 1261404	26-09-89
		JP-A- 60092701	24-05-85
		JP-B- 63029527	14-06-88

US-A-5057104	15-10-91	US-A- 5486172	23-01-96
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		JP-T- 6509734	02-11-94
		US-A- 5425728	20-06-95
		WO-A- 9308715	13-05-93
		US-A- 5423803	13-06-95

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		CN-A- 1064600	23-09-92
		EP-A- 0533863	31-03-93



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Search result: 1 of 1

(WO/1996/025979) DEVICE FOR USE IN THE LASER TREATMENT OF BIOLOGICAL TISSUE (VARIANTS THEREOF)

[Biblio. Data](#) [Description](#) [Claims](#) [National Phase](#) [Notices](#) [Documents](#)

Latest bibliographic data on file with the International Bureau



Pub. No.: WO/1996/025979 International Application No.: PCT/RU1995/000211
 Publication Date: 29.08.1996 International Filing Date: 27.09.1995
 Chapter 2 Demand Filed: 24.09.1996

IPC: A61B 18/22 (2006.01), A61C 1/00 (2006.01), A61B 17/00 (2006.01), A61B 18/20 (2006.01)

Applicant: ALTSHULER, Grigory Borisovich [RU/RU]; (RU).

Inventor: ALTSHULER, Grigory Borisovich; (RU).

Priority Data: 95102749 24.02.1995 RU

Title: DEVICE FOR USE IN THE LASER TREATMENT OF BIOLOGICAL TISSUE (VARIANTS THEREOF)

Abstract: The devices, comprising two or three pulse lasers (3, 4, 20), are provided with a system for the automated optimisation of the parameters pertaining to the radiation of the two lasers and to the type and method of treatment applied to each type of biological tissue. The outputs from at least one receiver (15) for receiving data on the condition of the biological tissue (16) being treated are connected to the inputs of the control unit (1) whose output signals are applied to electronic switches (5, 6, 26) incorporated in the links between each laser (3, 4, 20) and a power supply unit (2). The devices also include a controllable irrigation system (17) for irrigating the treatment zone and a mixing system for mixing the laser beams. The latter system comprises reflecting mirrors (7, 21) and selectively reflecting mirrors (8, 25) and makes it possible to produce independent radiation outputs.

Designated States: AT, AU, BR, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KR, MX, NO, NZ, PL, PT, RU, SE, SI, US.
 European Patent Office (EPO) (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Publication Language: Russian (RU)

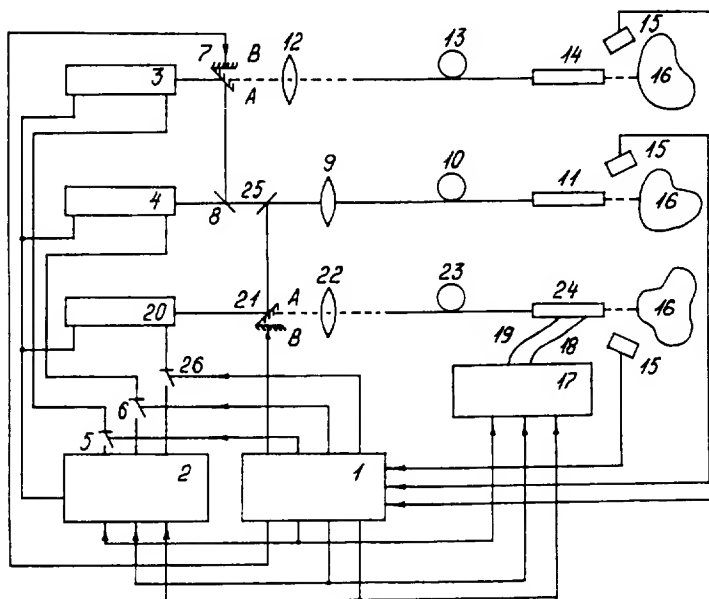
Filing Language: Russian (RU)

МЕЖДУНАРОДНАЯ ЗАЯВКА, ОПУБЛИКОВАННАЯ В СООТВЕТСТВИИ
С ДОГОВОРом О ПАТЕНТНОЙ КООПЕРАЦИИ (РСТ)

(51) Международная классификация изобретения ⁶ : A61N 5/06	A1	(11) Номер международной публикации: WO 96/25979 (43) Дата международной публикации: 29 августа 1996 (29.08.96)
(21) Номер международной заявки: PCT/RU95/00211 (22) Дата международной подачи: 27 сентября 1995 (27.09.95) (30) Данные о приоритете: 95102749 24 февраля 1995 (24.02.95) RU (71)(72) Заявитель и изобретатель: АЛЬТШУЛЕР Григорий Борисович [RU/RU]; 96240 Санкт-Петербург, Пулковское шоссе, д. 5, корп. 1, кв. 97 (RU) [ALT-SHULER, Grigory Borisovich, St.Petersburg (RU)].		(81) Указанные государства: AT, AU, BR, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KR, MX, NO, NZ, PL, PT, RU, SE, SI, US, европейский патент (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Опубликовано С отчетом о международном поиске.

(54) Title: DEVICE FOR USE IN THE LASER TREATMENT OF BIOLOGICAL TISSUE (VARIANTS THEREOF)

(54) Название изобретения: УСТРОЙСТВО ДЛЯ ЛАЗЕРНОЙ ОБРАБОТКИ БИОЛОГИЧЕСКОЙ ТКАНИ (ЕГО ВАРИАНТЫ)



(57) Abstract

The devices, comprising two or three pulse lasers (3, 4, 20), are provided with a system for the automated optimisation of the parameters pertaining to the radiation of the two lasers and to the type and method of treatment applied to each type of biological tissue. The outputs from at least one receiver (15) for receiving data on the condition of the biological tissue (16) being treated are connected to the inputs of the control unit (1) whose output signals are applied to electronic switches (5, 6, 26) incorporated in the links between each laser (3, 4, 20) and a power supply unit (2). The devices also include a controllable irrigation system (17) for irrigating the treatment zone and a mixing system for mixing the laser beams. The latter system comprises reflecting mirrors (7, 21) and selectively reflecting mirrors (8, 25) and makes it possible to produce independent radiation outputs.

В устройства, состоящие из двух или трех импульсных лазеров (3, 4, 20), введена система автоматической оптимизации параметров излучения этих лазеров, типов и режимов обработки для каждого вида биологической ткани. Выходы хотя бы одного приемника информации (15) о состоянии обрабатываемой биоткани (16) соединены с входами блока управления (1), выходные сигналы которого подаются на электронные ключи (5, 6, 26), установленные в цепях соединения каждого лазера (3, 4, 20) с блоком питания (2). В устройства включены также управляемая система орошения (17) зоны обработки и система смешивания излучения лазеров, состоящая из отражательных зеркал (7, 21) и селективно отражательных зеркал (8, 25), предусматривающая возможность и независимых выходов излучений.

ИСКЛЮЧИТЕЛЬНО ДЛЯ ЦЕЛЕЙ ИНФОРМАЦИИ

Коды, используемые для обозначения стран-членов РСТ на титульных листах брошюр, в которых публикуются международные заявки в соответствии с РСТ.

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Устройство для лазерной обработки биологической ткани (его варианты)

Область техники

Изобретение относится к медицинской технике и может быть
5 использовано в хирургии, ортопедии и стоматологии для обработки
мягких и твердых биологических тканей.

Предшествующий уровень техники

Известно устройство для обработки тканей зуба лазерным
излучением (патент WO 90/01907, A61C 5/00, дата публикации 08.03.90),
10 содержащее последовательно расположенные вдоль оптической оси
импульсный лазер и средство доставки излучения к зубу, включающее
отрезок оптического волокна, вход которого оптически сопряжен с
выходом лазера, и наконечник, вход которого оптически сопряжен с
выходом оптического волокна, а выход является выходом устройства.
15 Причем, в качестве лазера может быть использован как неодимовый, так и
гольмиевый или эрбиевый лазеры.

Основным недостатком данного устройства является невозможность
быстрой замены одного лазера на другой в зависимости от типа
обрабатываемой ткани, а также высокая опасность нанесения лазерной
20 травмы.

Известно также лазерное устройство для лечения зубов, которое
является наиболее близким по технической сущности и принято за
прототип (патент WO 90/12548, A 61C 5/00, дата публикации 01.11.90).

Это устройство содержит блок управления, два импульсных лазера,
25 оптические оси которых параллельны, расположенные на оптической оси
второго лазера, фокусирующую систему и отрезок оптического волокна с
наконечником. На оптический осях обоих лазеров расположены под углом
45° к осям оптически сопряженные между собой, фокусирующей системой
и оптическим волокном зеркала. Зеркало, расположенное на оси первого
30 лазера отражательное, а на оси второго лазера - дихроичное,
т.е. селективно отражательное для длины волны излучения первого лазера
и прозрачное для длины волны излучения второго.

Основным недостатком прототипа является недостаточная
эффективность его применения при переходе от режима одного типа
35 обработки к другому и опасность нанесения травмы, связанная с
отсутствием системы определения вида обрабатываемой ткани.

Раскрытие изобретения

Задача, на решение которой направлено заявляемое изобретение,
заключается в создании устройства для лазерной обработки биологической
40 ткани, выполняющего все виды лазерных операций в хирургии, ортопедии
и стоматологии, с обеспечением при этом возможности быстрого перехода
от одного типа обработки к другому и минимальной инвазивности.

Указанная задача решается при осуществлении изобретения за счет
достижения технического результата, заключающегося в оптимизации

режимов обработки и параметров лазерного излучения в зависимости от типа обработки и вида биологической ткани.

Указанный технический результат при осуществлении изобретения достигается тем, что в устройство для лазерной обработки биологической
5 ткани содержащее блок управления, выходы которого соединены с блоком питания лазеров, импульсные лазеры, оптические оси которых параллельны, оптически сопряженные отражательное и селективно
отражательное для длины волны первого лазера и прозрачное для длины волны второго лазера зеркала, установленные на осях первого и второго
10 лазеров соответственно, установленные на оптической оси второго лазера фокусирующую систему и оптическое волокно с наконечником, выход которого является оптическим выходом устройства, введен хотя бы один
приемник информации о состоянии биологической ткани, вход которого сопряжен с местом воздействия на ткань, а выход соединен с входом
15 блока управления, выходы которого соединены с входами электронных ключей, установленных в цепях соединения каждого лазера с блоком питания. Отражательное зеркало установлено с возможностью вывода его
из хода излучения, а на оптической оси первого лазера последовательно по ходу излучения расположены фокусирующая система и оптическое
20 волокно с наконечником, выход которого является другим оптическим выходом устройства.

Более эффективно указанный технический результат достигается тем, что в устройство для лазерной обработки биологической ткани, содержащее блок управления, выходы которого соединены с блоком
25 питания лазеров, импульсные лазеры, оптические оси которых параллельны, оптически сопряженные отражательное и селективно отражательное для длины волны первого лазера и прозрачное для длины волны второго лазера зеркала, установленные на осях первого и второго
лазеров соответственно, установленные на оптической оси второго лазера фокусирующую систему и оптическое волокно с наконечником, выход
30 которого является оптическим выходом устройства, введен третий импульсный лазер, оптическая ось которого параллельна оптическим осям двух других лазеров, а на его оси установлено отражательное зеркало, причем отражательные зеркала установлены с возможностью вывода их из
хода излучения. На оптической оси второго лазера за селективным
35 зеркалом установлено второе селективно отражательное для длины волны третьего лазера и прозрачное для длины волны первого и второго лазеров зеркало, оптически сопряженное с отражательным зеркалом, установленным на оси третьего лазера, с фокусирующей системой и
40 входом оптического волокна, расположенных на оси второго лазера. Кроме того, на каждой из осей первого и третьего лазеров последовательно по ходу излучения расположены фокусирующая система и оптическое волокно с наконечником, выходы которых являются оптическими входами устройства. Устройство также снабжено хотя бы

одним приемником информации о состоянии биологической ткани, вход которого сопряжен с местом воздействия на ткань, а выход соединен с входом блока управления, выходы которого соединены с входами электронных ключей, установленных в цепях соединения каждого лазера с блоком питания.

Приемник информации о состоянии биологической ткани может быть выполнен в виде спектроанализатора в области 200 - 1500 нм., вход которого оптически сопряжен с местом воздействия на ткань и состоящего из дисперсионного элемента, линейки фотодетекторов и элемента сравнения. Приемник информации о состоянии биологической ткани также может быть выполнен в виде фотоэлектрического приемника инфракрасного излучения, вход которого оптически сопряжен с местом воздействия на ткань посредством поворотного зеркала, расположенного на оптической оси лазера между выходным зеркалом лазера и фокусирующей системой через фильтр с полосой пропускания, исключающей попадание на приемник излучения лазера.

Приемник информации о состоянии биологической ткани может быть еще выполнен в виде акустического приемника, установленного таким образом, что направление его максимальной чувствительности составляет с направлением оптической оси на входе наконечника угол α , удовлетворяющий условию: $11^{\circ} < \alpha < 86^{\circ}$.

Электронный ключ может быть выполнен в виде полупроводникового или электровакуумного переключателя.

Дополнительно, устройство снабжено системой орошения зоны обработки, состоящей из резервуара для воды с водяным насосом и воздушного компрессора, соответствующие выходы которых объединены в наконечниках и являются ирригационными выходами устройства, а воздушный компрессор в месте соединения с воздухопроводами снабжен электромагнитными клапанами, подключенными к выходам блока управления через линии задержки.

Известно, что эффективность лазерной обработки биологической ткани с одновременным обеспечением низкой инвазивности (степени некроза) зависит от длины волны и мощности лазерного излучения, энергии и времени лазерного воздействия и, для некоторых видов ткани, жидкостного орошения зоны лазерной обработки (см., например, Proceeding of ... Laser-Tissue Interaction V 24-27, January 1994, Los Angeles, California Vol 2134A).

Исследования, проведенные автором, показали, что при этом необходима одновременная оптимизация указанных параметров для каждого вида биоткани. Иными словами, необходимы:

1. возможность выбора оптимальных длин волн излучений лазеров или их смеси,

2. регистрация процесса лазерной деструкции, вида и состояния биоткани и управления длиной волны, мощностью, энергией и временем лазерного действия,

3. система орошения зоны лазерной обработки.

5 Совокупность введенных в устройство хотя бы одного приемника информации о состоянии обрабатываемой биологической ткани, выход которого соединен с входом блока управления, и электронных ключей, установленных в цепях питания лазеров и управляемых выходными сигналами блока управления, представляют собой систему обратной связи,
10 которая обеспечивает автоматический контроль и оптимальное управление параметрами излучений лазеров в зависимости от вида и состояния обрабатываемой ткани и, тем самым, обеспечивает минимальную инвазивность.

 Необходимость автоматического контроля и управления вызвана
15 часто возникающей невозможностью визуального определения врачом состояния облучаемой ткани и ее вида.

 Наличие двух независимых выходов в одном устройстве благодаря возможности вывода отражательного зеркала из хода излучения первого лазера, а также возможность смешивания излучений двух лазеров
20 повышает эффективность работы при обработке биоткани.

 Наличие в одном устройстве для обработки биологической ткани трех лазеров с различными длинами волн излучений и независимыми выходами и с возможностью смешивания излучений обеспечивает наибольшую мобильность применения устройства и максимально
25 расширяет его возможности. Например, при одновременном воздействии гольмиевым и неодимовым лазерами на обильно кровонасыщенные органы снимается опасность кровотечения при несанкционированной перфорации крупных кровеносных сосудов, а сочетание излучений эрбиевого лазера с неодимовым и гольмиевым эффективно при обработке костных тканей и
30 твердых тканей зуба. Для смешивания излучения третьего лазера с двумя другими или каждым из них введены отражательное и селективное зеркала, установленные соответственно на осях третьего и второго лазеров, а возможность вывода отражательных зеркал из хода излучения и наличие дополнительных фокусирующих систем и оптических волокон
35 обеспечивает независимость трех оптических выходов устройства.

 Дополнительно введенная в устройство система орошения, управляемая электромагнитными клапанами, подключенными к выходам блока управления обеспечивает оптимальное сочетание режимов облучения и орошения ткани.

40 По сведениям автора совокупность изложенных в формуле изобретения признаков является новой, а само техническое решение удовлетворяет критерию "изобретательский уровень".

Краткое описание чертежей

Сущность изобретения поясняется на фигурах, где

фиг.1 - изображает схему устройства для лазерной обработки биоткани.

фиг.2 - схему вариантов выполнения и расположения приемников

5 информации о состоянии обрабатываемой биоткани.

фиг.3 - схему устройства при наличии трех лазеров

фиг.4 - систему ирригации.

фиг.5 - блок-схему блока управления.

Устройство для лазерной обработки биологической ткани (фиг.1)
10 состоит из блока управления 1, соединенного с ним блока питания 2, импульсных лазеров 3 и 4, соединенных с блоком питания через электронные ключи 5 и 6, которые подключены к выходам блока управления 1. На оптических осях лазеров 3 и 4 расположены, соответственно, отражательное зеркало 7 и селективное зеркало 8,
15 которые оптически сопряжены между собой, фокусирующей системой 9 и выходным торцом оптического волокна 10 с наконечником 11, расположенных на оптической оси лазера 4. Селективное зеркало 8 отражательно для излучения с длиной волны лазера 3, но прозрачно для излучения с длиной волны лазера 4. Расположенное на оптической оси
20 лазера 3 отражательное зеркало 7 подключено к выходу блока управления 1 и в положении А устанавливается под углом 45° к оси, а в положении В параллельно ей. На этой же оси вслед за зеркалом последовательно на ходу излучения расположены фокусирующая система 12 и оптическое волокно 13 с наконечником 14. К входу блока управления 1 подключен
25 электрический выход приемника информации о состоянии биологической ткани 15, вход которого сопряжен с местом воздействия на биоткань 16. Система ирригации 17 подключена к тем же выходам блока управления 1, что и блок питания 2, а ее водяной и воздушный выходы 18 и 19 объединены в наконечнике 11 (14).

30 Лучший вариант осуществления изобретения

На фиг.2 представлен вариант устройства с тремя лазерами 3, 4, 20. На оптической оси лазера 20 установлено отражательное зеркало 21, которое так же, как и отражательное зеркало 7, подключено к блоку управления 1, и в положении А устанавливается под углом 135° к
35 оптической оси, а в положении В параллельно ей. На этой же оптической оси расположены фокусирующая система 22 и входной торец оптического волокна 23 с наконечником 24. Между фокусирующей системой 9 и селективным зеркалом 8 установлено второе селективное зеркало 25, которое оптически сопряжено с зеркалом 21, фокусирующей системой 9 и
40 входным торцом оптического волокна 10. Селективное зеркало 25 отражательно для излучения с длиной волны лазера 20, но прозрачно для излучений с длинами волн лазеров 3 и 4. Блок питания 2 соединен с лазером 20 через электронный ключ 26.

Разновидностями приемника информации 15 о состоянии биоткани 16 могут быть как спектроанализатор 27 (фиг.3), вход которого оптически сопряжен с местом воздействия на биоткань 16, и который состоит из дисперсионного элемента 28, линейки фотодетекторов 29, 5 расположенной в месте соответствующему области длин волн 200 - 1500нм и элемента сравнения 30; так и фотоэлектрический приемник инфракрасного излучения 31, оптически сопряженный с местом воздействия на биоткань 16 посредством оптического волокна 13 (10, 23), фокусирующей системы 12 (9, 22) и поворотного зеркала 32, 10 расположенного между фокусирующей системой 12 (9, 22) и зеркалом 8 или непосредственно перед выходным зеркалом лазера 3 (20). Перед оптическим входом фотоэлектрического приемника 31 установлен инфракрасный фильтр 33, полоса пропускания которого исключает попадание на фотоэлектрический приемник 31 излучения лазера. В 15 качестве приемника информации 15 о состоянии биологической ткани 16 может быть и акустический приемник 34, расположенный вблизи места воздействия на ткань так, что направление его максимальной чувствительности составляет с оптической осью излучения на выходе наконечника 11 (14, 24) угол α , лежащий в пределах от 11^0 до 86^0 .

20 В связи с тем, что число приемников информации о состоянии биоткани может колебаться от одного до девяти (по каждому виду, около каждого наконечника), количество входов блока управления может быть равно девяти).

Система орошения зоны обработки 17, изображенная на фиг.4 25 состоит из резервуара для воды с водяным насосом 35, к которому присоединена водопроводящая трубка 18, и воздушного компрессора 36. Присоединенные к воздушному компрессору 36 воздухопроводящие трубки 19 снабжены электромагнитными клапанами 37, 38, 39, которые 30 подключены к тем же выходам блока управления 1, что и блок питания 2, через линии задержки 40, 41, 42.

Устройство работает следующим образом. Излучения лазеров 3, 4, 20, в случае нахождения отражательных зеркал 7 и 21 в положении В, пройдя фокусирующие системы 9, 12, 22, отрезки оптических волокон 10, 13, 23 и наконечники 11, 14, 24 поступают на оптические выходы 35 устройства.

Если отражательные зеркала 7 и 21 находятся в положении А, излучение лазера 3, отразившись от зеркала 7 попадает на селективное зеркало 8 и, отразившись от него, направляется вдоль оптической оси 40 лазера 4. Аналогично, при наличии лазера 20, излучение этого лазера , отразившись от зеркала 21, а затем от селективного зеркала 25 также направляется вдоль оптической оси лазера 4. В результате, в связи со свойством селективных зеркал 8 и 25, в фокусирующую систему 9 и, тем самым на оптический выход наконечника 11 могут поступать излучения 40 всех трех лазеров одновременно.

Выбор вида приемника информации 15 о состоянии биоткани 16 зависит от вида ткани и режима обработки, а также, от вида наконечника. При работе с неконтактными наконечниками основная часть излучения эрозионного факела, возникающего из-за свечения удаляемых частиц биоткани лежит в видимой и ближних ультрафиолетовой и инфракрасной областях спектра (200 - 1500нм) и является причиной невозможности визуального наблюдения вида и состояния биоткани. Спектральный состав излучения эрозионного факела зависит от вида биоткани, поэтому необходим спектральный анализ этого излучения, которое попадает на дисперсионный элемент 28 спектроанализатора 27, разлагается в спектр и попадает на линейку фотодетекторов 29, соединенную с элементом сравнения 30. Уровень выходного электрического сигнала элемента сравнения 30 соответствует конкретной комбинации длин волн спектра излучения эрозионного факела. Электрический сигнал от элемента сравнения 30 спектроанализатора 27 поступает на вход блока управления 1, где вырабатывается сигнал изменения режима излучения лазеров.

Работа с контактными наконечниками связана с нагреванием лазерным излучением торца рабочего инструмента (волокно или сапфировый наконечник) до определенной температуры, достаточной для разрушения биоткани. Нагрев места воздействия сопровождается возникновением инфракрасного излучения, которое передается по волокну наконечника 11 (14, 24) и отрезку оптического волокна 10 (13, 23) в направлении, обратном ходу лазерного излучения, отражается от поворотного зеркала 32, проходит инфракрасный фильтр 33 и попадает на фотоэлектрический приемник 31. Электрический сигнал с выхода фотоэлектрического приемника 31 поступает в блок управления 1, где в зависимости от параметров этого сигнала вырабатывается сигнал остановки, продолжения или изменения режима работы лазера.

Экспериментально установлено, что тепловое излучение, возникающее при работе с контактными наконечниками находится в глубокой инфракрасной области. В этой области чувствительность фотоэлектрических приемников очень мала. Спектральная область излучения лазеров также лежит в инфракрасной области. Поэтому полоса пропускания инфракрасного фильтра 33 согласована со спектральной чувствительностью фотоприемника 31, с окном прозрачности оптического волокна 13 и обеспечивает исключение попадания на фотоприемник 31 излучения лазеров 3, 4, 20.

Продукты лазерного разрушения биоткани разлетаются со сверхзвуковой скоростью, и в следствие резкого изменения давления из-за сопротивления среды генерируется акустическая волна. Для различных тканей амплитуда акустической волны различна. Амплитуда акустической волны регистрируется акустическим приемником 34, электрический сигнал с которого поступает на блок управления 1, где синтезируется сигнал временной остановки излучения или изменения режима работы

лазера в зависимости от типа обрабатываемой ткани или в случае превышения энергии лазерного импульса над порогом разрушения биоткани, что влияет на степень лазерного некроза.

5 Прекращение, в случае необходимости, режима излучения лазеров в соответствии с сигналами спектроанализатора 27, фотоэлектрического или акустического приемников 31 и 34 происходит с помощью
10 быстродействующих электронных ключей 5, 6, 26. Сигнал с блока управления 1 подается на управляющий вход электронного ключа 5, (6, 26) размыкая цепь питания каждого из лазеров. Прекращение импульса
15 излучения эффективно, если время отключения питания меньше длительности импульса излучения. (Длительность импульса излучения может быть 150 - 500 мксек.). Поэтому в качестве электронного ключа должен использоваться элемент с высоким быстродействием. Такими управляемыми ключами являются полупроводниковые или
20 электрорвакуумные переключатели, время срабатывания которых не превышает 100 мкс.

Орошение биоткани с помощью ирригационной системы 17 происходит следующим образом. Из резервуара для воды с водяным насосом 35 вода заполняет водопроводящие трубки 18. В случае
25 необходимости орошения ткани сигналы из блока управления 1 поступают на электромагнитный клапан 37 (38, 39), который открывает поступление воздуха под давлением из воздушного компрессора 36 в воздухопровод 19. Концы водо- и воздухопроводящих трубок 18 и 19 расположены в наконечниках 11 (14, 24) так, что поступление воды на ирригационные
30 выходы устройства происходит при подаче воздуха по принципу пульверизатора.

Сигналы из блока управления 1 поступают на электромагнитные клапаны 37 (38, 39) через линии задержки 40 (41, 42) одновременно с сигналами запуска импульсов генерации лазеров 3 (4, 20).

30 Орошение биоткани водой должно происходить в промежутках между импульсами излучения лазеров (с целью избежать нежелательное рассеяние излучения и повысить эффективность орошения), поэтому длительность времени задержки линий задержки 40 (41, 42) равна временной длительности импульсов излучения лазеров с учетом времени
35 поступления воздуха к концам трубок 19.

Пример конкретной реализации заявляемых устройств состоит в следующем:

Блок управления 1 (фиг. 5) состоит из усилителя входных сигналов с интегратором, восьмиканального десятиразрядного аналого-цифрового
40 преобразователя (АЦП) с последовательным интерфейсом max 192 серии, процессора РС-104 с кварцевым генератором и восьмиканального тринадцатиразрядного цифро-аналогового преобразователя (ЦАП) с последовательным интерфейсом max 540 серии. Выходные сигналы ЦАП являются выходами блока управления 1, по трем из которых, кроме

сигналов запуска импульсов генерации, поступают сигналы, определяющие величину энергии накопительных конденсаторов блока питания 2.

В качестве лазеров используются лазеры: Nd:YAG (длина волны 1.06 мкм или 1.32 мкм), Ho:YAG (длина волны 2,09 мкм) и Er:YAG (длина волны 2,94 мкм). В качестве дисперсионного элемента 28-стеклянная призма, в качестве фотодетекторов 29 - кремниевые полупроводниковые фотодиоды ФД-256, а в качестве фотоэлектрического приемника инфракрасного излучения 31 - германиевый фотодиод ФД-9. Элемент сравнения 30- микросхема К554СА3 или LM-111. Акустический приемник 34 - микрофон В&К4138.

Промышленная применимость

Таким образом, предлагаемые устройства, за счет совокупности заявляемых признаков, обеспечивая оперативное управление, с возможностью варьирования в широком диапазоне параметрами лазерного излучения, позволяют проводить хирургические процедуры на биотканях в качестве либо скальпеля, либо коагулятора, либо деструктора в зависимости от требуемых типов, режимов и сочетаний работы лазеров, ориентированных на минимальную травматичность при данном виде воздействия на данную биоткань.

Формула изобретения

1. Устройство для лазерной обработки биологической ткани, содержащее блок управления (1), выходы которого соединены с блоком питания (2) лазеров, импульсные лазеры (3, 4), оптические оси которых
5 параллельны, оптически сопряженные отражательное зеркало (7) и селективно отражательное для длины волны первого лазера (3) и прозрачное для длины волны второго лазера (4) зеркало (8), которые расположены на оптических осях первого и второго лазеров соответственно, установленные на оптической оси второго лазера (4)
10 фокусирующую систему (9) и оптическое волокно (10) с наконечником (11), выход которого является оптическим выходом устройства, отличающееся тем, что в него введен хотя бы один приемник информации (15) о состоянии биологической ткани (16), вход которого сопряжен с местом воздействия на биоткань (16), а выход соединен с входом блока
15 управления (1), выходы которого соединены с входами электронных ключей (5, 6), установленных в цепях соединения каждого лазера с блоком питания (2), кроме того, отражательное зеркало (7) установлено с возможностью вывода его из хода излучения, а на оптической оси первого лазера (3) последовательно по ходу излучения расположена фокусирующая
20 система (12) и оптическое волокно (13) с наконечником (14), выход которого является другим оптическим выходом устройства.

2. Устройство для лазерной обработки биологической ткани, содержащее блок управления (1), выходы которого соединены с блоком питания (2) лазеров, импульсные лазеры (3, 4, 20), оптические оси
25 которых параллельны, оптически сопряженные отражательное зеркало (7) и селективно отражательное для длины волны первого лазера (3) и прозрачное для длины волны второго лазера (4) зеркало (8), которые расположены на оптических осях первого и второго лазеров соответственно, установленные на оптической оси второго лазера (4),
30 фокусирующую систему (9) и оптическое волокно (10) с наконечником (11), выход которого является оптическим выходом устройства, отличающееся тем, что в него введен третий импульсный лазер (20), оптическая ось которого параллельна оптическим осям двух других лазеров, установлено отражательное зеркало (21), причем отражательные
35 зеркала (7, 21) установлены с возможностью вывода их из хода излучений, а на оптической оси второго лазера (4) за селективным зеркалом (8) установлено второе селективно отражательное для длины волны третьего лазера (20) и прозрачное для длин волн первого и второго лазеров (3, 4) зеркало (25) оптически сопряженное с отражательным зеркалом (21),
40 установленным на оптической оси третьего лазера (20), фокусирующей системой (9) и входом оптического волокна (10), расположенных на оси второго лазера (4), на каждой из осей первого и третьего лазеров (3, 20) последовательно по ходу излучения расположены фокусирующая (12, 22) система и оптическое волокно (13, 23) с наконечником (14, 24), выходы

которых являются другими оптическими выходами устройства, снабженного также хотя бы одним приемником информации (15) о состоянии биологической ткани (16), вход которого сопряжен с местом воздействия на биоткань (16), а выход соединен с входом блока управления (1), выходы которого соединены с входом электронных ключей (5, 6, 26), установленных в цепях соединения каждого лазера (3, 4, 20) с блоком питания (2).

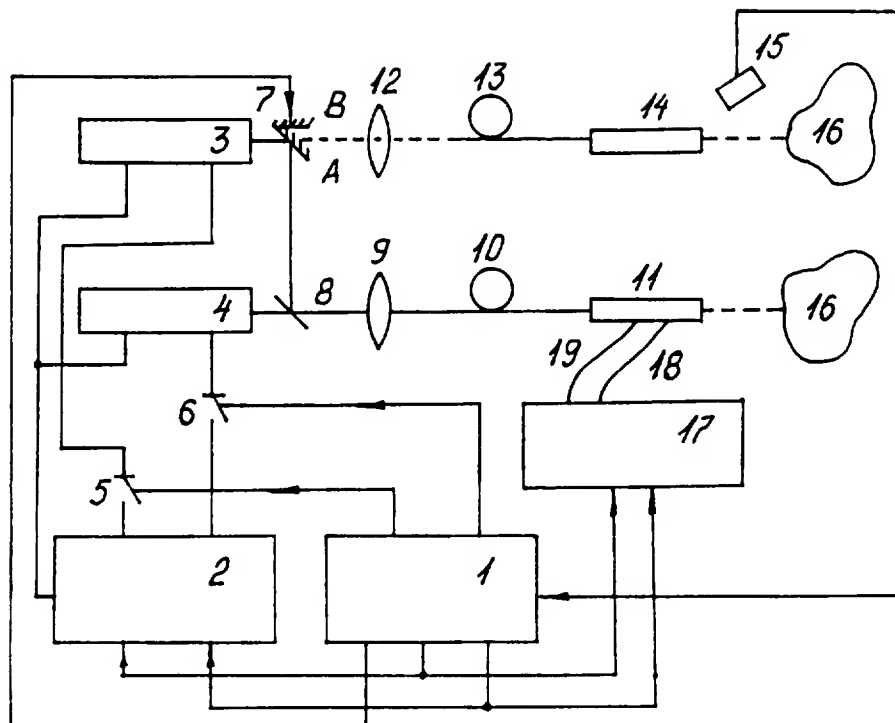
3. Устройство по п.1, 2, отличающееся тем, что приемник информации (15) о состоянии биологической ткани (16) выполнен в виде спектроанализатора (27) в области 200 нм - 1500 нм, вход которого оптически сопряжен с местом воздействия на биоткань (16), и состоящего из дисперсионного элемента (28), линейки фотодетекторов (29) и элемента сравнения (30).

4. Устройство по п. 1, 2, отличающееся тем, что приемник информации (15) о состоянии биологической ткани (16) выполнен в виде фотоэлектрического приемника (31) инфракрасного излучения, вход которого оптически сопряжен с местом воздействия на биоткань (16) посредством поворотного зеркала (32), расположенного на оптической оси лазера (3, 4, 20) между выходным зеркалом лазера (3, 4, 20) и фокусирующей системой (9, 12, 22), через фильтр (33) с полосой пропускания, исключающей попадание на приемник (31) излучения лазера.

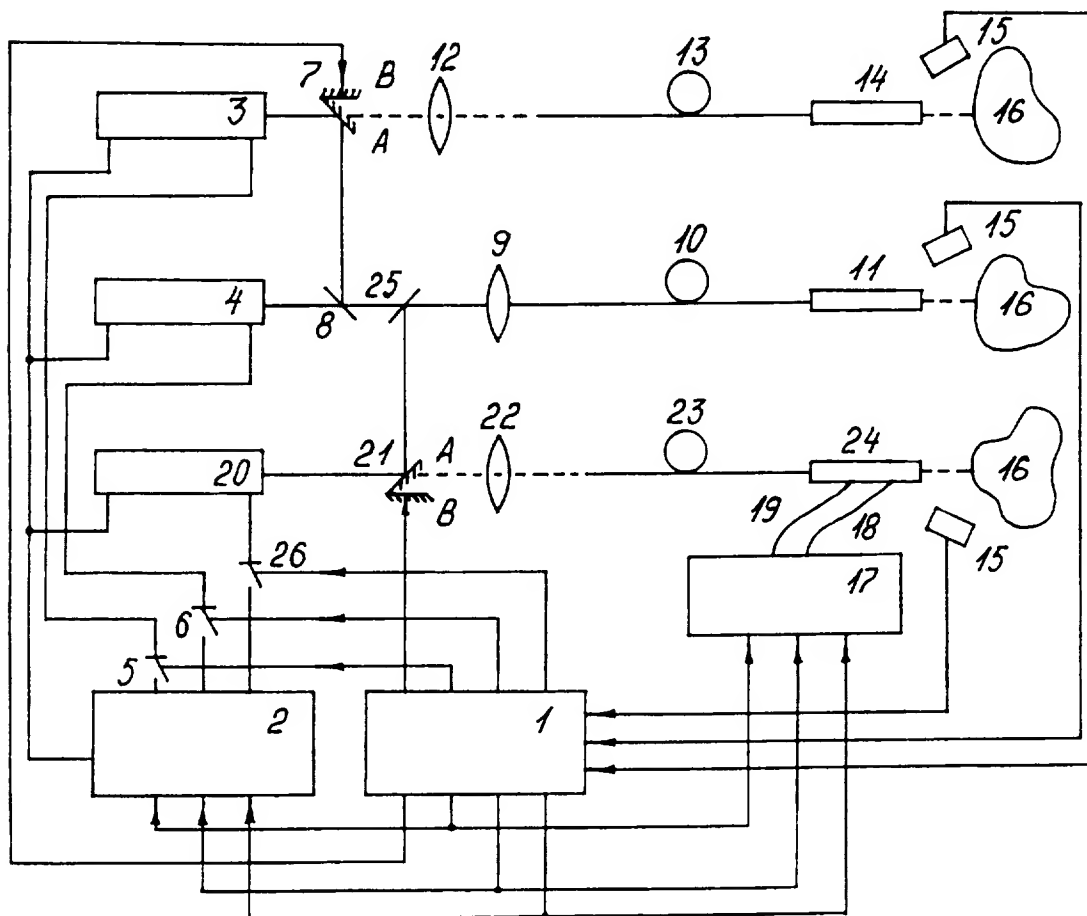
5. Устройство по п. 1, 2, отличающееся тем, что приемник информации (15) о состоянии биологической ткани (16) выполнен в виде акустического приемника (34), установленного таким образом, что направление его максимальной чувствительности составляет с направлением оптической оси на выходе наконечника (11, 14, 24) угол α , удовлетворяющий условию: $11^{\circ} < \alpha < 86^{\circ}$.

6. Устройство по п. 1,2, отличающееся тем, что электронный ключ (5, 6, 26) выполнен в виде полупроводникового или электровакуумного переключателя.

7. Устройство по п. 1, 2, отличающееся тем, что оно дополнительно снабжено системой орошения (17), состоящей из резервуара для воды с водяным насосом (35) и воздушного компрессора (36), соответствующие выходы (18, 19) которых объединены в наконечниках (11, 14, 24) и являются ирригационными выходами устройства, а воздушный компрессор (36) в месте соединения с воздухопроводами (19) снабжен электромагнитными клапанами (37, 38, 39), подключенными к выходам блока управления (1) через линии задержки 40, 41, 42.

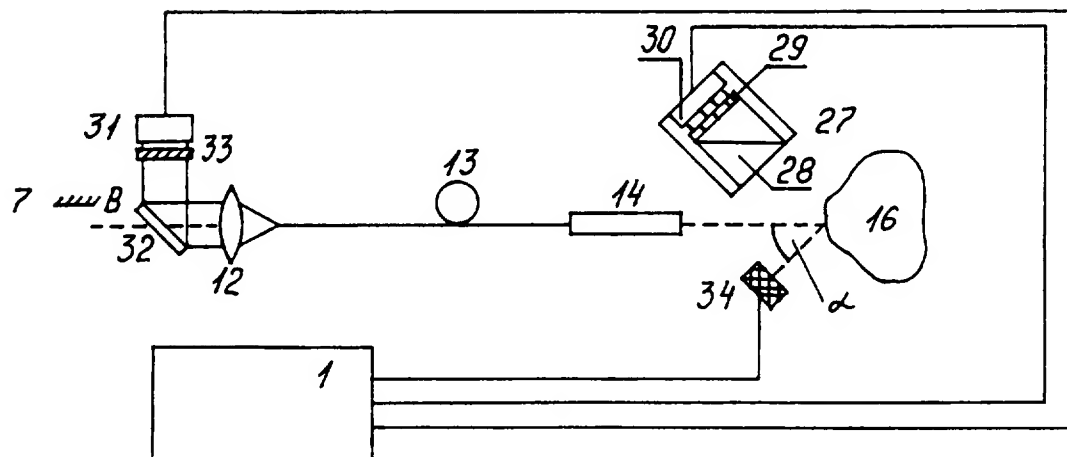


ФИГ. 1

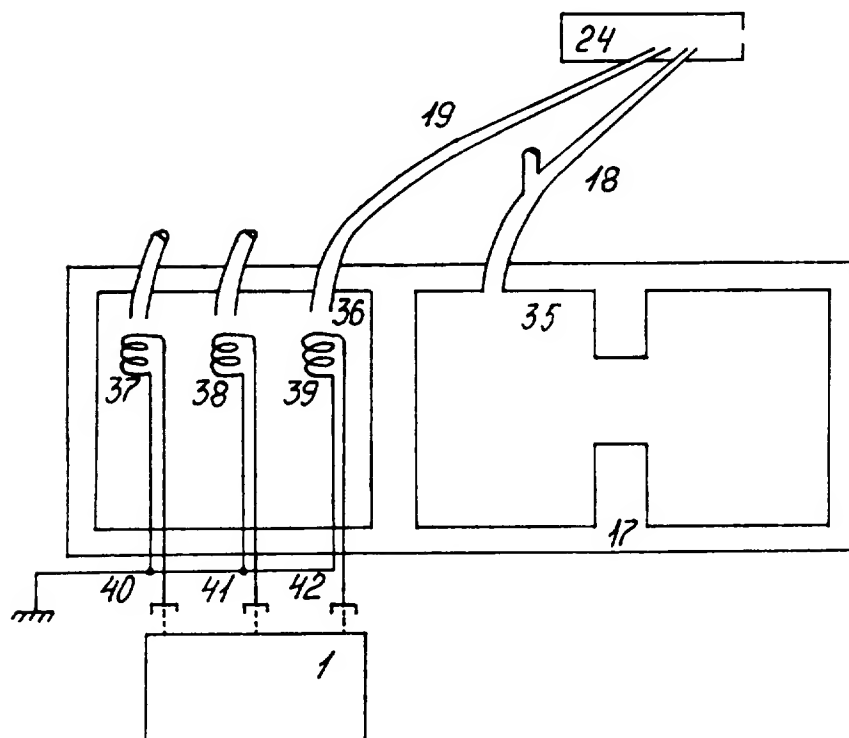


ФИГ. 2

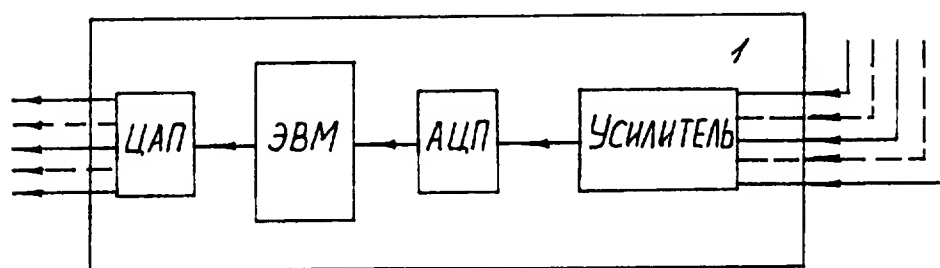
2/2



ФИГ. 3



ФИГ. 4



ФИГ. 5

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61N 5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61N 5/06, A61B 17/36, A61C 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, A1,90/12548 (VASSILIADIS, ARTHUR et al), 01 November 1990 (01.11.90), the description, pages 1,5-9, Figs. 1-4.	1,3-7,2-7
A	EP, A2,0429297 (HAMAMATSU PHOTONICS K.K.) 29 May 1991 (29.05.91), the description, pages 1-5, Figs. 1-4	1,3-7,2-7
A	EP, A1,0320080 (DIAMANTOPOULOS, COSTAS), 14 June 1989 (14.06.89), the description, pages 1,4-8, Fig. 4	1,3-7,2-7
A	EP, A1,0253734 (SOCIETE CIVILE de RECHERCHE "SCR RECHERCHES et DEVELOPPEMENT"), 20 January 1988 (20.01.88)	1,3-7,2-7



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

11 January 1996 (11.01.96)

Date of mailing of the international search report

23 January 1996 (23.01.96)

Name and mailing address of the ISA/ RU

Authorized officer

Facsimile No.

Telephone No.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/RU 95/00211

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SU, A, 4836203 (CARL-ZEISS-STIFTUNG), 06 June 1989 (06.06.89)	1,3-7,2-7

ОТЧЕТ О МЕЖДУНАРОДНОМ ПОИСКЕ

Международная заявка No
PCT/RU 95/00211

А. КЛАССИФИКАЦИЯ ПРЕДМЕТА ИЗОБРЕТЕНИЯ: A61N 5/06
Согласно Международной патентной классификации (МКИ-6)

В. ОБЛАСТИ ПОИСКА:

Проверенный минимум документации (Система классификации и индексов) МКИ-6: A61N 5/06, A61B 17/36, A61C 5/00

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A	WO, A1.90/12548(VASSILIADIS,ARTHUR et al), 01 ноября 1990 (01.11.90), описание,с.1,5-9,фиг.1-4	1,3-7,2-7
A	EP, A2.0429297 (HAMAMATSU PHOTONICS K.K) 29 мая 1991 (29.05.91),описание с.1-5,фиг.1-4	1,3-7,2-7
A	EP, A1.0320080 (DIAMANTOPOULOS,COSTAS), 14 июня 1989 (14.06.89),описание,с.1,4-6,фиг.4	1,3-7,2-7
A	EP, A1.0253734 (SOCIETE CIVILE de RECHERCHE "SCR RECHERCHES et DEVELOPPEMENTS"), 20 января 1988 (20.01.88)	1,3-7,2-7

☒ последующие документы указаны в продолжении графы С ☐ данные о патентах-аналогах указаны в приложении

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Дата действительного завершения международного поиска
11 января 1996 (11.01.96)

Дата отправки настоящего отчета о международном поиске
23 января 1996 (23.01.96)

Наименование и адрес Международного поискового органа:
Всероссийский научно-исследовательский институт государственной патентной экспертизы, Россия, 121858, Москва, Бережковская наб. 30-1
факс (095)243-33-37, телетайп 114313 ПОДАЧА

Уполномоченное лицо:

Е.ДЕНДИКОВ

тел.(095)240-56-85

ОТЧЕТ О МЕЖДУНАРОДНОМ ПОИСКЕ

Международная заявка No
PCT/RU 95/00211

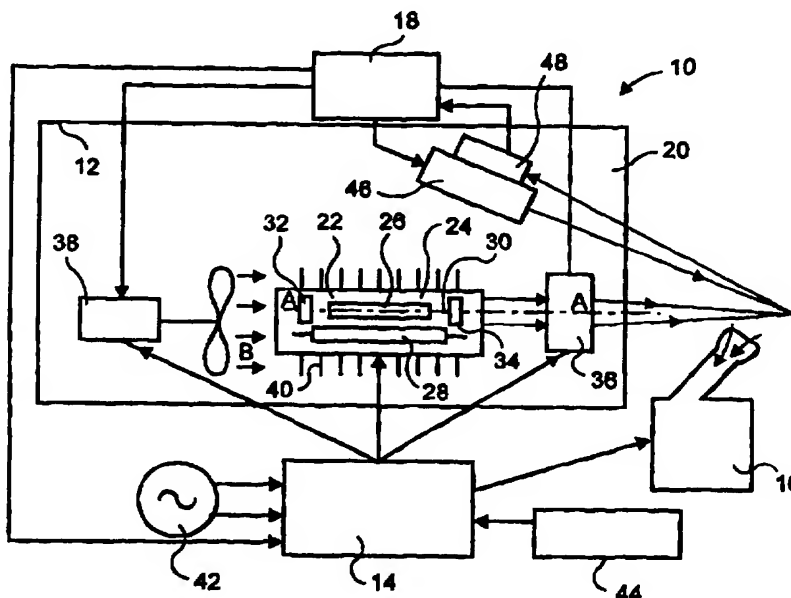
С. (Продолжение) ДОКУМЕНТЫ, СЧИТАЮЩИЕСЯ РЕЛЕВАНТНЫМИ

Категория *	Ссылки на документы с указанием, где это возможно, релевантных частей	Относится к пункту No.
A	SU. A. 4836203 (CARL-ZEISS-STIFTUNG), 06 июня 1989 (06.06.89)	1.3-7.2-7



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61N 5/06	A1	(11) International Publication Number: WO 96/28212 (43) International Publication Date: 19 September 1996 (19.09.96)
(21) International Application Number: PCT/US96/02984 (22) International Filing Date: 5 March 1996 (05.03.96) (30) Priority Data: 95102934 9 March 1995 (09.03.95) RU 08/610,211 4 March 1996 (04.03.96) US (71) Applicant: INNOTECH USA, INC. [US/US]; P.O. Box 492, Ardsley, NY 10502 (US). (74) Agent: FRIDMAN, Lawrence, G.; 66 Mount Prospect Avenue, Clifton, NJ 07013 (US).		(81) Designated States: AM, AU, AZ, BG, BR, BY, CA, CN, CZ, EE, FI, GE, HU, IS, JP, KE, KR, LT, LV, MD, MK, MX, NO, NZ, PL, RO, SG, SI, SK, TR, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: LASER SURGICAL DEVICE AND METHOD OF ITS USE**(57) Abstract**

A laser surgical device (10) for vaporization of a living tissue consists of an operating laser assembly (22, 24, 26, 28, 30, 32, 34), a detecting arrangement (48), and a control unit (14). The operating laser assembly generates an operating beam having a predetermined wavelength corresponding to a peak absorption wavelength of water. The detecting arrangement is adopted for detecting a condition of an operated living tissue by receiving and reviewing a signal reflected from the operated living tissue so as to produce a control signal. The control unit controls characteristics of the operating beam based on the control signal, so that the depth of vaporization of the living tissue does not exceed 15 microns to 20 microns.

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LASER SURGICAL DEVICE AND METHOD OF ITS USE

FIELD OF THE INVENTION

This invention relates to medical lasers, and more particularly to a surgical laser device and a method of its use in the field of dermatology.

BACKGROUND OF THE INVENTION.

A variety of lasers have been used in modern dermatology for correction of inborn and acquired skin defects and diseases. One of the reasons for wide proliferation of the lasers in this field is that their properties support the medical postulate - "do not harm" a patient.

Drug therapy has been the most commonly used method of treatment in dermatology mainly because it is readily available, simple and less painful. However, drug intolerance, side effects, common allergic reactions as well as low efficiency in treatment of a substantial number of disorders often make this treatment less desirable.

A need for more efficient cure of dermatological defects and diseases made surgical involvement quite popular in this area of medicine. As to the surgical methods of treatment of skin disorders, doctors are often compelled to resort to such procedures as: dissection followed by transplantation, use of ultrasound and cryotherapy, application of magnetic fields of ionizing radiation, electrocoagulation, utilizing of plasma currents, etc. These surgical methods are used in spite of a great number of drawbacks

and harmful side effects which include: destructive nature of the treatment, protractive healing process, high risk of hypopigmentation, possibility of atrophy, destruction of a skin texture, formation of scars, damage to an adjacent skin area including healthy regions. These problems are often alleviated when a surgeon uses local methods of treatment having short and fixed duration of action at a specified depth of a skin integument. This is one of the reasons why lasers have become recently the instrument of choice for many dermatologists.

Currently, lasers having different wavelength of laser irradiation are used in dermatology. Examples of such lasers are: excimer, ruby, argon laser; alexandrite and garnet laser; tunable semiconductor laser; etc. These devices generate laser beams having the wavelength in the visible range of the spectrum (0.4-0.7 μm) as well as in the invisible, the UV range (0.18-0.40 μm). For instance, infrared lasers include a set of CO₂ lasers (with the wavelength of 10.6 μm), variations of neodymium lasers (with the wavelength of 1.06 μm), etc. These lasers are produced by Candela Laser Corporation and are described by "Lasers in Medicine" Tashkent, 1989.

In spite of the fact that these lasers maintain a short duration of action and provide certain localization in the plane of the action, they do not guarantee control of the treatment, especially as to the depth of penetration in the skin integument. Thus, use of these lasers does not eliminate such negative consequences as formation of hypotrophic scars and penetration of a laser beam into the area of healthy skin.

It is a matter of general knowledge that a layer of water practically does not allow optical irradiation at certain

wavelength to pass therethrough. This region of the spectrum is typically known as the "window of non-transparency" and includes the following wavelength ranges: 1.25-1.40; 1.7-2.1; 2.5-3.1 and 5.5-7.5 microns. At these ranges optical irradiation is strongly absorbed by water and by living tissue which also consists of up to 90 percent of water. Such absorption leads to a rapid heating of water and vaporization of the treated living tissue. At these wavelengths a laser beam acquires an important quality, that is that laser irradiation can not penetrate deeply in to living tissue substantially consisting of water. As a result, a scattered laser beam propagates in living tissue only within the range which does not exceed the depth of 15-20 microns and does not destroy adjacent tissue. Such a mode of operation of a laser can be implemented only at specific levels of power density and energy, predetermined rate and duration of the pulse and only when a temporary stability of all these characteristics is achieved during a surgical procedure.

One of such known devices is the aluminum-yttrium-erbium garnet laser having the wavelength of 2.94 μm of laser irradiation. Initial reports about stomatological application of this laser appeared in 1989. However, its properties such as energy pulse of 1-2 J; the wavelength of 2.94 μm and the pulse rate of 1 Hz enabled doctors to use this laser as surgical device in the field of dermatology. The first reports of such use became known in Germany and Slovenia in 1991.

A schematic diagram of FIG.1 illustrates that such a device consists of a power unit, a cooling unit, a laser cavity and an articulated mirror light-guide unit. In view of the multiple reflections of the laser beam in the articulated mirror light-guide, the efficiency of the device is quite low

and does not exceed 60 percents at the wavelength of 2.94 μm . This makes it necessary to sustain energy input of the laser irradiation at the level 2.5-3.0 J and the operating power of the power unit at 300 W. Naturally, a laser of such high power has to have a very efficient cooling system. Therefore, a special water cooling system was provided in this prior art device. In view of that, the weight of the device was 70 kgs with overall dimensions of 0.5 m³. Thus, large weight and dimensions as well as instability of the laser beam characteristics greatly limited employment of this prior art laser in dermatology.

The water cooling system was necessary in the high powered prior art device to keep the temperature of the active element within 20 \pm 10 $^{\circ}$ C range. When this temperature range was exceeded the thermolens effect developed in the active element which resulted in considerable laser beam scattering and in the loss of energy in the focal plane of a treated tissue.

One way of resolving these problems is through the formation of a more efficient laser system which lacks the articulated mirror light guide and requires substantially less power. This makes it possible the replacement of the water cooling system by its air cooling counterpart. Such changes ultimately led to a substantial reduction of the weight and overall dimensions of the laser assembly.

Thus, there has been a considerable need for an efficient hand held laser surgical device usable in the field of dermatology which is capable of providing and controlling a predetermined depth of skin penetration and does not damage healthy regions of tissue adjacent the operation site.

SUMMARY OF THE INVENTION

One aspect of the present invention provides a laser surgical device for vaporization of a living tissue. The device consists of an operating laser assembly, a detecting arrangement and a control unit. The operating laser assembly generates an operating beam having a predetermined wavelength corresponding to a peak absorption wavelength of water. The detecting arrangement is provided for detecting conditions of an operated living tissue by receiving and reviewing a radiation signal reflected from the operated living tissue and producing a control signal. The control unit controls and adjusts characteristics of the operating beam based on the control signal, so that the depth of vaporization of the living tissue does not exceed 15-20 microns. The device also includes a power unit, a focusing arrangement for focusing the operating beam at the operated living tissue, a guide light unit generating a guide light beam for targeting the operating beam at the operated living tissue and a cooling unit for cooling of at least a portion of the operating laser assembly. The suction arrangement is provided for removal of disintegrated tissue products from the area of the operated living tissue.

A further aspect of the invention provides the operating laser assembly consisting of at least an operating laser element emitting the operating beam and exciting arrangement for its exciting. A handpiece is adopted for convenient positioning in the hands of an operator. The handpiece has interior and exterior parts and at least a portion of the operating laser assembly and focusing arrangement are situated within the interior part of the handpiece. At least portions of the cooling unit, the detecting arrangement and the control

unit are also situated within the interior portion of the handpiece.

Another aspect of the invention provides a device in which at least a portion of the operating laser assembly is positioned within the housing and the cooling unit is a fan producing an air flow extending longitudinally within the interior portion of the handpiece.

Still another aspect of the invention provides the device in which the exciting arrangement is positioned outside the handpiece and is connected to the operating laser assembly by a plurality of optical fibers.

Still further aspect of the invention provides a device with the operating laser element consisting of working and auxiliary portions. The working portion is situated in the handpiece, whereas the auxiliary portion and the exciting arrangement are situated outside the handpiece. The main and auxiliary portions of the operating laser element are connected through a light guide consisting of a plurality of optical fibers.

Yet another aspect of the invention provides the device in which the wavelength of the operating beam emitted by the operating laser element is selected from the group consisting of 1.25-1.40, 1.7-2.1; 2.5-3.1 and 5.5-7.5 microns. The laser medium of the operating laser element is selected from the group consisting essentially $\text{Y}_3\text{Al}_5\text{O}_{12}$: Nd; $\text{Gd}_3\text{Ga}_5\text{O}_{12}$; Cr, Ce, Nd; MgF_2 : Co; BaYb_2F_8 : Er; LiYF_4 : Er: Tm, Ho; $\text{Y}_3\text{Sc}_2\text{Al}_3\text{O}_{12}$: Cr, Er; $(\text{Y}, \text{Er})_3\text{Al}_5\text{O}_{12}$; HF (chemical) and CO (gaseous).

Alternatively, the method of surgical vaporization of a living tissue can be provided. The method comprises the steps of generating an operating laser beam having a predetermined wavelength corresponding to a peak absorption wavelength of

water and detecting a condition of operating living tissue by receiving and reviewing a radiation signal reflected from the tissue and producing a control signal. A further step of the method is controlling and adjusting characteristics of the operating beam based on the control signal, so that the depth of the vaporization of the living tissue does not exceed 15-20 microns.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages and features of the invention are described with reference to exemplary embodiments, which are intended to explain and not to limit the invention, and are illustrated in the drawings in which:

FIG.1 shows a prior art laser device;

FIG.2 shows one embodiment of a laser surgical device of the invention;

FIG. 3 shows another embodiment of the laser surgical device;

FIG. 4 shows a portion of a further embodiment of the laser surgical device;

FIG. 5 shows a simplified embodiment of the laser surgical device;

FIG. 6 shows another simplified embodiment of the laser surgical device;

FIG. 7 illustrates alternative positions of the lens of focusing arrangement;

FIG. 8 shows a laser surgical device having substantially cylindrical focusing lens;

FIG. 9 shows a laser surgical device with the focusing lens movable about shifted axis;

FIG. 10 shows application of an accessory lens to the laser surgical device;

FIGS. 11 and 12 illustrate different patterns of laser beam images;

FIGS. 13 and 14 illustrate further patterns of laser beam images;

FIG. 15 illustrates conditions of beam scanning at a preset program; and

FIG. 16 illustrates conditions of beam scanning when the laser beam is in the slot form.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Although specific embodiments of the invention will now be described with reference to the drawings, it should be understood that the embodiments shown are by way of examples only and merely illustrative of but few of many possible specific embodiments which represent application of the principles of the invention. Various changes and modifications obvious to one skilled in the art to which the invention pertains are deemed to be within the spirit, scope and contemplation of the invention as further defined in the appended claims.

It was indicated hereinabove that the optical irradiation in the wavelength region corresponding to the "window of non-transparency" is very efficiently absorbed by water and living tissue. The operating beam of the laser surgical device of the present invention efficiently performs within such entire wavelength region. As a result of application of the laser beam to the targeted area of a patient, a local vaporization of the top skin layer occurs at the maximum depth of 10-20 microns. The diameter of the irradiated spot on

the skin is about 10 mm and the density is in the range of 5-50 J/cm².

Referring now to the drawings, in which there is shown in FIG. 2 an apparatus 10 for performing of a laser surgery. The apparatus 10 consists of the following main units: a compact surgical laser instrument or a handpiece 12, a power supply unit 14 producing high-voltage potential pulses with tunable parameters, a suction unit or suction apparatus 16 for suction of disintegrated skin products resulted from application of an operating laser beam to a targeted area and a control unit 18. The handpiece formed with a housing 20 is adopted to be conveniently held in the hands of an operator. It is best illustrated in FIG.2 that a laser cavity 22 is provided within the interior area of the housing 20. An operating laser assembly 24 is situated within the laser cavity and consists of an active laser element or rod 26, an exciting arrangement 28 and an optical resonator 30. The exciting arrangement which is adopted for exciting of the operating laser element can be any conventional exciting device such as, for example, a flash lamp or a diode laser.

The optical resonator 30 includes a mirror 32 having high reflective capabilities and positioned rearwardly of the laser element and a semi-reflective operating mirror 34 situated forwardly of the laser element so as to face a variable focusing lens 36. The mirrors of the optical resonator are disposed in the coaxial manner to a longitudinal axis A-A of the laser rod 26 and operating laser beam. The focusing lens 36 which is at least partially positioned within the housing 20 is typically operated by a micromotor on command from the control unit 18. A desired position of the focusing lens 36 can be also arranged manually by a medical personnel

before or during a surgery. The optical resonator 30 is adopted to align and amplify the laser beam, whereas the focusing lens 36 directs it to the targeted area. In order to facilitate efficient delivery of the light energy from the exciting arrangement 28 to the operating laser element 26, the interior of the laser cavity can be covered by a material of high reflectivity.

A cooling arrangement 38 is provided within the housing 20 rearwardly of the laser cavity 22. The cooling arrangement can be of any known type producing an axial stream of gaseous coolant. In the preferred embodiment of the invention the cooling arrangement is a fan 38 which generates an axially directed air stream B extending longitudinally in the interior of the housing 20. In order to increase efficiency of the cooling process the exterior of the laser cavity 22 is formed with a plurality of ribs 40 extending outwardly therefrom. Thus, upon activation of the fan, axially directed air stream B is blown over the exterior of the laser cavity 22, including the ribs 40 reducing their temperature. The air stream B during its travel within the handpiece is directed through openings in the housing (not shown) to the exterior parts of the focusing lens 36, so as to prevent pollution of the lens by disintegrated skin products resulted from the surgery. Upon reaching the operated area of the skin, the air stream B also facilitates removal of the disintegrated tissue products from the site of the surgery and reduces effect of an unpleasant odor on a medical personnel.

Longitudinal distribution of the elements of the invention within the housing 20 helps to reduce the dimensions and facilitates efficient delivery of the air coolant and reduction of temperature of the laser cavity and through-

out the interior area of the handpiece. Furthermore, use of air cooling system results in better stability of temperature and other characteristics of the laser cavity, especially during and after multiple thermocycling.

The surgical apparatus 10 is energized through a source of standard electrical supply 42 or through a set of batteries 44. In order to eliminate any potential shock hazard specially upon switching the power from the source of standard electrical supply to the battery unit, a power interlock switch can be provided.

The power supply unit 14 generates electrical voltage pulses which are converted by the exciting arrangement or the flash lamp 28 into light pulses. In the laser cavity 22, after being directed to the laser rod 26, such light pulses are converted into laser pulses having shorter duration of emission compared to the voltage pulses. The wavelength of the laser irradiation is determined by the type of the laser rod or active element utilized by the surgical apparatus. In the preferred embodiment of the invention Er:YAG (erbium) laser is used as the active element or laser rod 26 of the surgical apparatus. The laser rod made of this material emits the electromagnetic energy corresponding to the wavelength of the "window of non-transparency" of water. The wavelength of this laser is 2.94 μm and is very close to the maximum absorption wavelength of water, which is about 3 μm . Thus, at this wavelength of the operating laser beam a great portion of its energy is absorbed by the operated living tissue which consists up to 90 percent of water.

The essential requirement for the materials used in the active element of the operating laser is that the wavelength of their irradiation belongs to the "window of non-

transparency" region of the spectrum. Therefore, the laser medium of the active element of the invention can be selected from, but is not limited to, the following group of materials which forms a part of this category: $\text{Y}_3\text{Al}_5\text{O}_{12}$: Nd (wavelength 1.33 μm); $\text{Gd}_3\text{Ga}_5\text{O}_{12}$: Cr, Ce, Nd (wavelength 1.42 μm); MgF_2 : Co (wavelength 1.75 μm); BaYb_2F_8 : Er (wavelength 2.0 μm); LiYF_4 : Er, Tm, Ho (wavelength 2.06 μm); $\text{Y}_3\text{Sc}_2\text{Al}_3\text{O}_{12}$: Cr, Er (wavelength 2.8 μm); $(\text{Y}, \text{Er})_3\text{Al}_5\text{O}_{12}$ (wavelength 2.94 μm); HF- chemical (wavelength 2.6-3.0 μm) and CO-gaseous (wavelength 5.0-6.0 μm).

This wavelength of the operating laser beam belongs to the infrared region of the spectrum and is invisible to the naked eyes of a surgical operator. In view of that, an operator can not observe the emission of the operating laser beam from the forefront of the handpiece. This might cause erroneous surgical steps raising serious questions of security in the medical treatment. To eliminate this drawback, in the invention a guide light unit 46 generating a continuous, visible guide light beam is provided. Such guide light unit can be He:Ne laser, semiconductor laser, light-emitting diodes or any other suitable source of visible radiation. In the embodiment of the invention illustrated in FIG.2 such guide light unit 46 is a semiconductor laser providing a very low power, continuous laser beam. Unlike the Er:YAG laser, the semiconductor laser emits the beam in the visible region of the spectrum. The guide light beam is adopted to indicate the focal point of the operating laser beam as a visible light spot before the operating laser beam is applied. That is the operating beam is applied to the same area as the guide light beam spot. Therefore, an operator can start the operating laser after the guide light beam spot appears at the desired

location. Thus, the continuous guide light laser beam serves aiming function simplifying targeting of the invisible pulse operating beam. In use, upon activation of the operating laser as well as the guide lasers, the continuous and the pulse beams are delivered to the targeted area. The operating laser can be easily focused at the targeted area based on the image of the guide light laser there. The disintegrated skin products accumulated at the site of the surgery are ultimately removed and disposed by the suction unit 16.

In the embodiments of FIGS. 2 and 3 the suction unit is designed as a device independent from the handpiece and energized by the power supply unit 14 of the surgical device. Nevertheless, forming the suction unit as a part of the handpiece is also contemplated.

In the alternative embodiment the cooling arrangement can be positioned outside the handpiece. For instance, it can be associated with the power unit in such manner that a stream of cooling air is delivered to the interior of the handpiece through a flexible piping or similar arrangement.

In operation of the FIG. 2 embodiment, to excite the operating laser, high voltage is developed in the power supply unit 14 and applied across the flash lamp 28. In the laser cavity 22 the delivery of the light energy from the flash lamp is facilitated by the highly reflective interior surface thereof. The energy from the flash lamp 28 is absorbed by the medium of the laser rod 26, so that the molecules in the laser medium are transferred from the ground state to the excited state. As those molecules return to their ground state, they emit photons of a particular wavelength. Part of the light emanates from the laser rod. The light is returned to the rod by the mirrors 32 and 34. The returned photons

react with molecules of the laser medium in the excited state to cause those molecules to return to the ground state and themselves emit photons of the particular frequency. Thus, the emitted photons are in phase with the photons striking the molecules and directed in the same direction as the original photons. In the operating laser the photons traveling between the mirrors 32 and 34 follow a specific paths, so that the photons resonate in particular modes at common frequency and phase. Eventually, the light between the mirrors 32 and 34 reaches such level of intensity that its substantial amount passes through the semi-reflective mirror 34 and is directed by the focusing lens 36 to the targeted area of the skin of a patient as an operating beam.

FIG. 3 illustrates the embodiment of the invention in which the laser surgical device is formed with two working cavities. An auxiliary cavity 17 is associated with the power supply unit 14. This cavity contains the exciting arrangement such as a flash lamp 28 and is connected through an activated fiber optic arrangement 19 to a main laser cavity 15. Similar to the embodiment of the FIG. 2, the main laser cavity 15 contains the active element or laser rod 26 and the optical resonator 30 having two mirrors 32 and 34. In operation, high voltage developed in the power supply unit 14 is applied to the exciting arrangement 28 of the auxiliary cavity 17 generating impulses of light energy. These impulses are delivered to the active element 26 situated in the main cavity 15 by means of the activated fiber optic arrangement 19.

In the embodiment of FIG. 3 the high voltage pulses energizing the flash lamp 28 are not transmitted directly to the handpiece. Instead, such high voltage pulses are delivered to the auxiliary cavity 17 situated remotely from the hand-

piece and an operator. This provides even higher degree of safety for the surgical device of the invention since chances of electrical shock hazards to the medical personal are effectively minimized.

Furthermore, since the exciting arrangement or the flash lamp 28 is positioned outside of the main cavity, the weight of the handpiece is greatly reduced simplifying manipulations of the device by a surgeon.

It is best illustrated in FIGS. 2 and 3 that during a surgery the condition of operated tissue is monitored by a detecting arrangement or detector 48 adopted to detect irradiation reflected from that tissue. One of the main functions of the detector 48 is to control the effect of the operating laser beam on the skin of a patient in general and specifically to control the depth of penetration of the operating laser beam and the depth of vaporization of the epidermis. In every individual case a doctor sets specific characteristics of the laser irradiation to produce the required effect. If a predetermined depth of penetration of the operating laser beam and/or the thickness of the vaporized layer of a skin are achieved, the detector 48 generates a signal directed to the control unit 18 which in turn produces a correcting signal to the power unit or other units of the surgical device. Similar signals can be also produced when the prearranged levels of the energy density, power density or other characteristics of the operating laser are attained. This is necessary to exclude possibility of deeper penetration of the operating laser beam and/or damaging an adjacent healthy skin tissue. The intensity of the reflected light radiation from the skin of a patient depends upon such factors as: type and stage of a disease, color of a skin, general

condition of a patient, the depth of a treated skin layer, etc. For each individual patient, considering the initial level of optical irradiation, such value of intensity characterizes a condition of an area of the skin treated by the laser surgical device of the invention. The detecting arrangement 48 can be made utilizing a wide variety of photosensitive elements, photoresistors, photodiodes and similar devices. If a photosensitive element is used to form the detector 48, the light reflected from the targeted area of the skin produces a flow of electrons in the photosensitive element directed towards its cathode and generates an electrical current or control signal for forwarding to the control unit 18. When photoresistors are utilized, the electrical resistance of the detector 48 varies depending upon the level of intensity of the light reflected from the operated tissue and received by the detector 48. The signal to the control unit 18 is based on such resistance.

FIG. 4 schematically illustrates a part of the laser assembly of another embodiment of the invention in which only portions of the active element and optical resonator are positioned in the main working cavity 21 situated in the handpiece. To accommodate such arrangement an auxiliary cavity 23 is provided. The exciting arrangement 28 and a first or auxiliary part 25 of the active element are situated within the auxiliary laser cavity 23. A distal end 29 of the first part 25 of the active element faces the mirror 32 having high reflectivity, whereas a proximal end thereof 31 is positioned at an end 37 of the light guide 41. To facilitate efficient delivery of the light energy from the exciting arrangement 28 to the first portion 25 of the active element the interior of the auxiliary cavity can be formed from a material having high

reflective properties. A second or working part 27 of the active element and a semi-reflective mirror 34 of the optical resonator are situated in the main working cavity 21. The distal end 33 of the second part 27 of the active element and the proximal end 31 of the first part thereof are optically connected through a fiber light guide 41. Both ends of the light guide situated in the vicinity of the active element can be manufactured as parts of the optical resonator. In this respect, the end 37 of the light guide positioned in the auxiliary cavity 23 can be formed as a mirror having characteristics facilitating passage of the laser irradiation from the first part 25 towards the second part 33 of the active element. To facilitate the required operating laser beam operation from the main cavity 21, the end 39 of the light guide situated thereinside can be formed as a mirror enabling passage of irradiation only in the direction of the second part 27 of the active element. As in the previously discussed embodiment of FIG.3, an operator is provided with an instrument devoid of electrical shock hazard and having considerably reduced weight. This is an important advantage of the present invention especially during prolonged surgical operations.

A further simplified embodiment of the laser surgical device is best illustrated in FIGS. 5 and 6. It is shown in FIG.5 that a handpiece 112 which resembles a housing of a hair drier contains an operating pulse laser 122, a cooling fan 138 and a light guide arrangement 146. In order to provide an axial air flow directed toward a patient, the fan 138 is positioned rearwardly of the operating laser. Two light-emitting diodes 145 and 147 of the light guide arrangement 146 are installed within the housing between the operating laser and the focusing lens 136. The light-emitting diodes

are arranged in such a manner that the distance between the images of their light guide beams 121 and 123 in the focal plane of the focusing lens 136 is substantially equal to the diameter of the spot of the operating beam 127 of the operating Laser 122 in this plane. Therefore, the targeted area of the operating beam spot can be identified by watching the visible images of the light guide beams. The dimensions of this operating beam spot can be adjusted by changing the distance between such visible images. The power supply unit 114 energizes not only the laser, fan and light guide arrangement but also the suction unit 116 positioned outside the housing. For the safety reasons all power feeding cables can be jacketed by earthen metal hoses. The pulse rate and the pulse energy of the operating laser 122 are set manually by generating a command from the control panel of the power supply unit 114. Similar to previously described embodiments, the suction unit 116 provides removal of the fragments of the disintegrated particles of skin developed during the surgery. The focusing lens 136 can be made of a quartz glass.

The laser surgical device of FIG. 6 is similar to that of FIG. 5. However, in FIG. 6 the exciting arrangement 135 is positioned outside the handpiece 112 and the impulses of light energy are delivered to the operating laser 122 by means of a light guide 137. In this respect, the instrument of FIG. 6 operates in a manner similar to the embodiment of FIG. 3. The modified embodiment of FIG. 6 in which a portion of the active laser element or rod is situated outside of the handpiece (see FIG. 4) is also contemplated.

In the embodiments illustrated in FIGS. 5 and 6 the focusing lens 136 is moved manually a predetermined distance. During such movement the position of images generated by the

light-emitting diodes 145 and 147, which determine the size of the operating laser spot in the focal plane, is automatically changed.

If the motion of the lens 136 is provided in the direction substantially perpendicular to the operating beam axis A-A, a series of laser beam images may be obtained in the focal plane. For example, FIG. 11 illustrates this condition for the normal and FIG. 12 for cylindrical lenses.

Upon motion of the focusing lens in the direction parallel to the axis of the beam it is possible to obtain a more complex image pattern, i.e. circular (see FIG. 13), spiral patterns (see FIG. 14).

Depending upon the type of operation, replacement of the focusing lens is possible in the present invention. Typically the most suitable lens is one having an optical element smoothly traveling along the axis of the operating laser beam, so that the optical element can be fixed at a prearranged intermediate position. In this respect, FIG. 7 illustrates the focusing lens 137 having three such intermediate positions.

The size of the operating laser spot in the focusing region can be regulated by a microdevice upon a signal from the control unit 18 (see FIG. 2). This can be also accomplished manually by an operator or according to a prearranged program. Thus, the size of the operating laser spot of the operating laser beam can be adjusted in the focal plane of the focusing lens up to the sizes at which irregularities of the laser spot are still acceptable.

The focusing lens shown in FIG. 8 produces the operating beam in the form of an oblong strip. This is achieved by using a semi-cylindrical lens 237. The required

changes in the form of this strip can be provided by rotating and guiding the lens 237 in a predetermined fashion.

The embodiment of the focusing lens 236 illustrated in FIG.9 enables the invention to produce a trace of movement of the focused operating laser beam in the form of a ring. This is achieved by rotating the focusing lens 236 about its axis B-B which is shifted a predetermined distance C from the axis A-A of the operating laser beam.

As to the embodiment of FIG. 10, it illustrates a supplemental focusing lens for the precise focusing of the operating laser beam on the targeted area. For this purpose it is advisable initially to fixedly attach the laser assembly 222 with the lenses 236, 239 and the mirrors 245, 247 at the prearranged condition. The visible guide light should be prealigned with the invisible operating laser beam. In this case it desirable to keep stationary at least a part of the patients body which is the subject of a surgery. A special device can be provided to accomplish this task.

The surgical device of the invention utilizes laser irradiation within the entire spectrum of the wavelength corresponding to the " window of non-transparency" of water. At the density of the laser irradiation of the operating beam spot $5-10 \text{ J/cm}^2$ and the diameter of the operating laser beam spot 3-10 mm, the depth of penetration of the operating laser beam of the invention into the epidermis does not exceed 10-20 microns. This occurs upon application of impulses having a very short duration of about 0.001 sec. After dehydration of the tissue, the spot of the operating laser beam produces only local vaporization of the top layer of the skin of a patient. This occurs without damaging in depth as well as

superficially healthy regions of epidermis surrounding the operated area. The treated area of the tissue can be increased by moving the spot of the operating laser beam over the surface of the skin. The depth of penetration of the operating laser beam into the living tissue can be manipulated by changing the frequency of the electromagnetic impulses. Typically, during a session having duration of 30-60 seconds about 50-100 impulses are provided.

The laser surgical device of the invention can be also utilized for disinfecting lesions by scattered infrared laser emission. The density of this type of emission does not produce damage to normal healthy skin. However, such emission eliminates staphylococcal colonies in the skin area damaged by a disease.

The optical system of the laser surgical device also enables a user to perform surgical operations which are followed by the laser photocoagulation and laser dissection including ablation of cancerous tumors. The present invention also facilitates removal of a benign tumor by vaporization of one layer of tissue at a time. This task can be accomplished through application of several laser impulses having a predetermined spot area to each part of the skin affected by the disease. The treatment is continued until "blood dew" appears on the skin and is typically followed by a course of drug treatment .

To carry out a therapy of the skin by infrared radiation to remedy, for example, face wrinkles, the laser surgical device of the invention can be used in combination with a scanning system of a preset scattered radiation. In order to utilize this treatment it is expedient to secure conditions of the beam scanning according to a preset program

(the spot diameter of the operating beam can vary in a predetermined fashion, the density of energy of the beam can be either variable or constant, see FIG.15). The same condition can be provided if the laser beam is in a form of a slot (see FIG.16).

The focused laser irradiation of the invention can be utilized for conducting of local surgeries, such as, for a example, dissection and removal of a furuncle or a pustule and consequent introduction of a medicine into the area of the incision.

The following examples are presented in order to provide more complete understanding of the invention. The specific techniques, conditions, materials and results set forth to illustrate the principles and practice of the invention are exemplary and should not be construed as limiting the scope of the invention.

Example 1

An Er:YAG laser was employed as an active element of the laser surgical device having a flash lamp as the exciting arrangement. The Er:YAG active element was interposed between two substantially flat resonator mirrors. The lasing occurred at the wavelength of 2.94 μm with the pulse duration 250 ± 50 microseconds, the pulse rate up to 1Hz and the pulse energy up to 2 J.

The shape of the operating laser beam was adjusted by the focusing arrangement. Since the Er:YAG laser beam belongs to the infrared region of the spectrum it was invisible to the naked eye of the operator. The position and dimensions of the laser spot of the operating laser beam on the skin of a patient were indicated with help of two guide

light beams generated by the guide semiconductor laser which emitted the beam in the visible region of the spectrum. The maximum diameter of each guide light laser beam was about 2.0 mm. The distance between projections of two guide light laser beams on the skin of a patient corresponded to the spot diameter of the Er:YAG laser on the same object. Thus, the position and diameter of the Er:YAG laser beam on the skin of the patient was determined by the position of two guide light laser beams emitted by the guide light semiconductor laser. The energy density of the Er:YAG laser was adjustable within the range between 1.0-10 J/cm². Considering that during the treatment the level of the pumping energy was about the same, the smaller the dimension of the Er:YAG laser beam, the higher its energy density. Upon reaching minimal focusing dimensions of the spot of Er:YAG laser beam on the skin of a patient a local vaporization of the tissue occurred at a depth of up to 1.5 mm. Visible vaporization from the epidermis took place when the energy density of the Er:YAG laser beam was about 50 J/cm².

Treatment of skin diseases of 48 patients was carried out by using surface vaporization of the epidermis by Er:YAG laser with 50 J/cm² maximum energy density. Among them were 15 patients with pointed condylomas, 8 patients with colloidal scars, 8 patients with warts on hands and feet, 10 patients with pointed hyperkeratoses, 7 patients with tattoos. Depending on the type of the disease or skin defect, the treatment was carried out by conducting 6-10 sessions, each consisting of 3-20 pulses.

During these sessions the diameter of the spot of the Er:YAG laser beam was 3-5 mm. The coagulation degree control was performed until appearance of the "blood dew"

symptom. As a result of such application of the laser beam to the skin of the patients there had been no changes detected in the peripheral blood content and no remote relapses of the disease revealed.

EXAMPLE 2

Unlike Example 1, there were two working cavities provided in the laser device of Example 2. In the first cavity electrical pulses were transformed into light pulses. Such light pumping pulses were received via the optical light guide in the second cavity. There the light pulses were transformed into the laser beam. The first cavity was situated at the power supply unit remotely from the patients and medical personnel. The second cavity was located within the handpiece of the surgical device. In this example another set of the working cavities was formed in such a manner that the first cavity contained the exciting arrangement and a portion of the operating laser rod, whereas the main part of the laser rod was situated in the second cavity. The cavities were also interconnected by the optical fiber light guide. The laser pulses received within the second cavity were of such pumping wavelength as to minimize losses in the optical light guide. The laser pulses generated in the second cavity were transformed into the laser irradiation beam operating of the required wavelength, for example, 2.94 μm .

WE CLAIM

1. A laser surgical device for vaporization of a living tissue, comprising:

an operating laser assembly generating an operating beam having a predetermined wavelength corresponding to a peak absorption wavelength of water;

a detecting arrangement for detecting a condition of an operated living tissue by receiving and reviewing a signal reflected from said operated living tissue and producing a control signal; and

a control unit for controlling and adjusting characteristics of said operating beam based on said control signal, so that the depth of vaporization of said living tissue does not exceed 15-20 microns.

2. The device of claim 1, further comprising a focusing arrangement for focusing said operating beam at said operated living tissue, a guide light unit generating a guide light beam for targeting of said operating beam at said operated living tissue and a cooling unit for cooling of at least said operating laser assembly.

3. The device of claim 2 further comprising a suction arrangement for removal of disintegrated tissue products from an area of said operated living tissue.

4. The device of claim 3, wherein said operating laser assembly comprises at least an operating laser element emitting said operating beam and exciting arrangement for exciting of said operating laser element.

5. The device of claim 4, further comprising a handpiece adopted for convenient positioning in hands of an operator, said handpiece having interior and exterior parts, at least a portion of said operating laser assembly and said focusing arrangement are situated within said interior part of said handpiece.

6. The device of claim 5, wherein at least portions of said cooling unit and said guide light unit are situated within the interior portion of said handpiece.

7. The device of claim 6, wherein said cooling unit is a fan producing an air stream extending longitudinally within said interior portion of said handpiece, so that said at least a portion of the operating laser assembly is situated within said air stream and is efficiently cooled.

8. The device of claim 5, wherein said exciting arrangement is positioned outside said handpiece and is connected to said operating laser element by at least one optical fiber.

9. The device of claim 5, wherein said operating laser element consists of working and auxiliary parts, said working part is situated within said handpiece, said auxiliary part and said exciting arrangement are situated outside of said handpiece, said working and auxiliary parts of the operating laser element are connected through a light guide consisting of at least one fiber.

10. The device of claim 1, wherein said detecting arrangement is selected from the group consisting essentially of photo elements, photo resistors and photo diodes.

11. The device of claim 1, wherein the wavelength of said operating beam is between 2.9 and 3.0 microns.

12. The device of claim 4, wherein said operating laser element is Er:YAG laser rod.

13. The device of claim 1, wherein the wavelength of said operating beam emitted by said operating laser element is selected from the group consisting of the following ranges 1.25-1.40; 1.7-2.1; 2.5-3.1 and 5.5-7.5 microns.

14. The device of claim 4, wherein a laser medium of said operating laser element is selected from the group consisting essentially $Y_3Al_5O_{12}$: Nd; $Gd_3Ga_5O_{12}$: Cr, Ce, Nd; MgF_2 : Co; $BaYb_2F_8$: Er; $LiYF_4$: Er:Tm, Ho; $Y_3Sc_2Al_3O_{12}$: Cr, Er; $(Y,Er)_3Al_5O_{12}$, HF (chemical) and CO(gaseous).

15. The device of claim 2, wherein said guide light unit provides a continuous low power beam and is selected from the group consisting essentially He:Ne laser, a semiconductor laser and light emitting diodes.

16. The device of claim 4, wherein said exciting arrangement is selected from the group consisting essentially a flash lamp and a diode laser.

17. A laser surgical device for vaporization of a living tissue comprising:

- a housing having interior and exterior portions;
- a laser cavity containing at least a part of an operating laser assembly generating an operating beam;
- a fan producing a cooling air stream;
- a focusing arrangement for focusing said operating beam;

a guide light unit for targeting said operating beam; said laser cavity, said fan, said focusing arrangement and said guide light unit are situated within said interior portion of the housing in such a manner that said fan is positioned rearwardly of said laser cavity and said guide light unit situated forwardly of said laser cavity facing said focusing lens, whereby said air stream extending longitudinally within said interior portion of the handpiece efficiently cools at least said laser cavity.

18. A method of surgical vaporization of a living tissue comprising the steps of:

- (a) generating an operating laser beam having a predetermined wavelength corresponding to a peak absorption wavelength of water;

- (b) detecting a condition of an operated living tissue by receiving and reviewing a radiation signal reflected from said operated living tissue and producing a control signal; and

- (c) controlling and adjusting characteristics of said operating beam based on said control signal, so that the depth of vaporization of said living tissue does not exceed 15-20 microns.

19. The method of claim 18, wherein the wavelength of said operating beam emitted by said operating laser element is selected from the group consisting of 1.25-1.40; 1.7-2.1; 2.5-3.1 and 5.5-7.5 microns.

20. The method of claim 18, wherein a laser medium of said operating laser element is selected from the group consisting essentially $\text{Y}_3\text{Al}_5\text{O}_{12}$: Nd; $\text{Gd}_3\text{Ga}_5\text{O}_{12}$: Cr, Ce, Nd; MgF_2 : Co; BaYb_2F_8 : Er; LiYF_4 : Er, Tm, Ho; $\text{Y}_3\text{Sc}_2\text{Al}_3\text{O}_{12}$: Cr, Er; $(\text{Y}, \text{Er})_3\text{Al}_5\text{O}_{12}$; HF (chemical) and CO(gaseous).

1 / 6

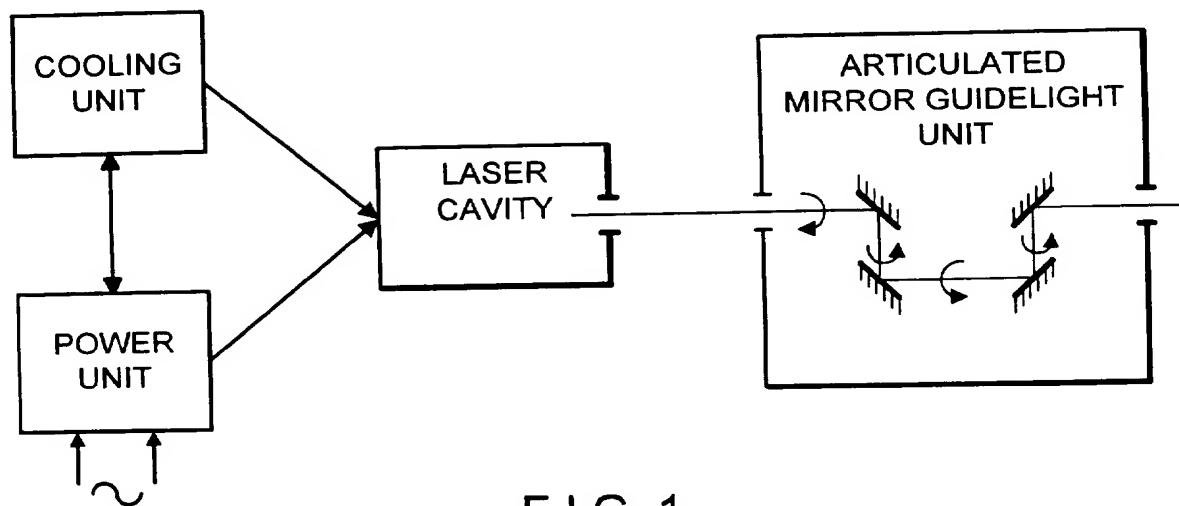


FIG. 1

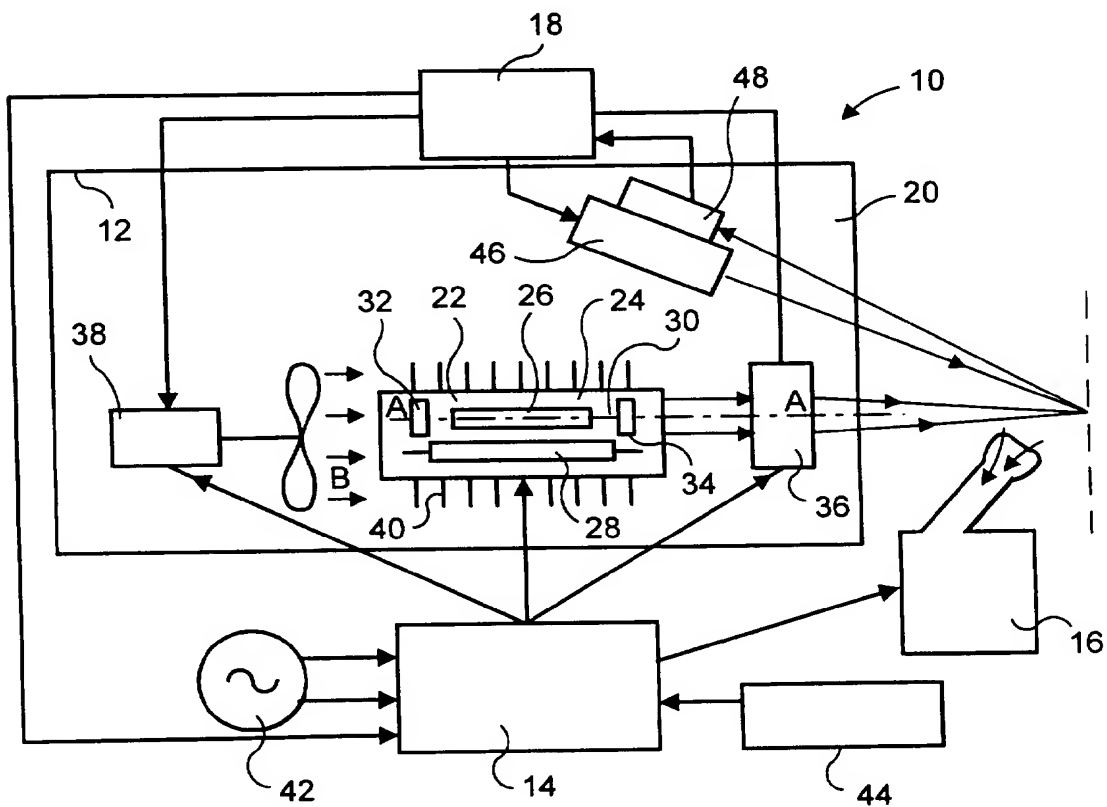


FIG. 2

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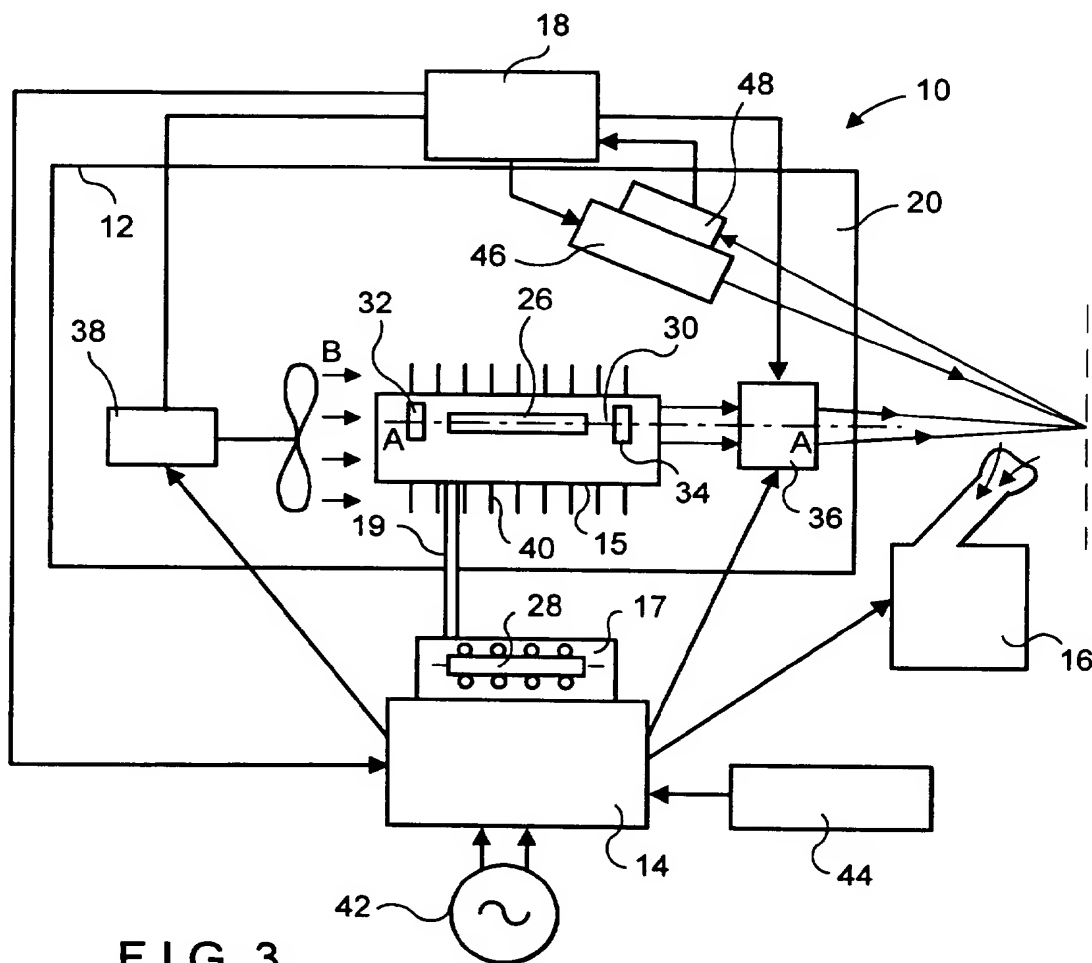


FIG. 3

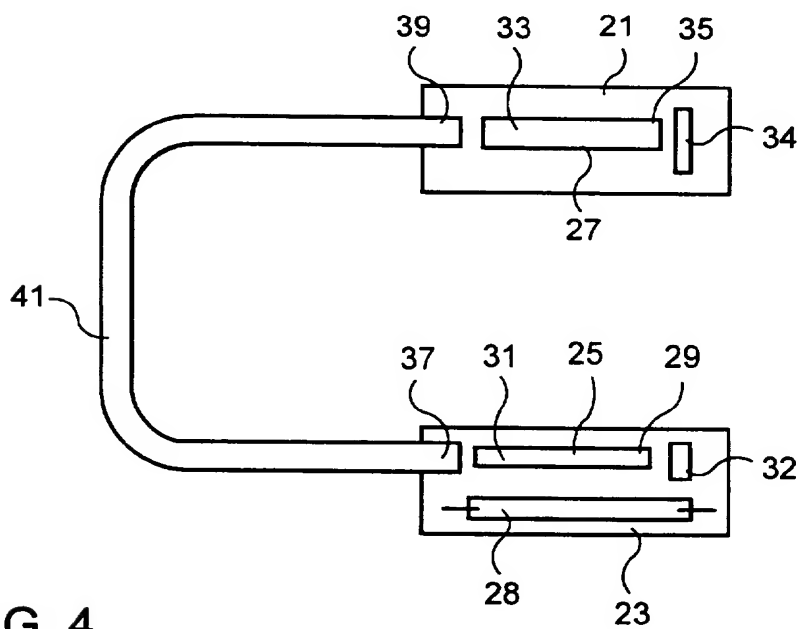


FIG. 4

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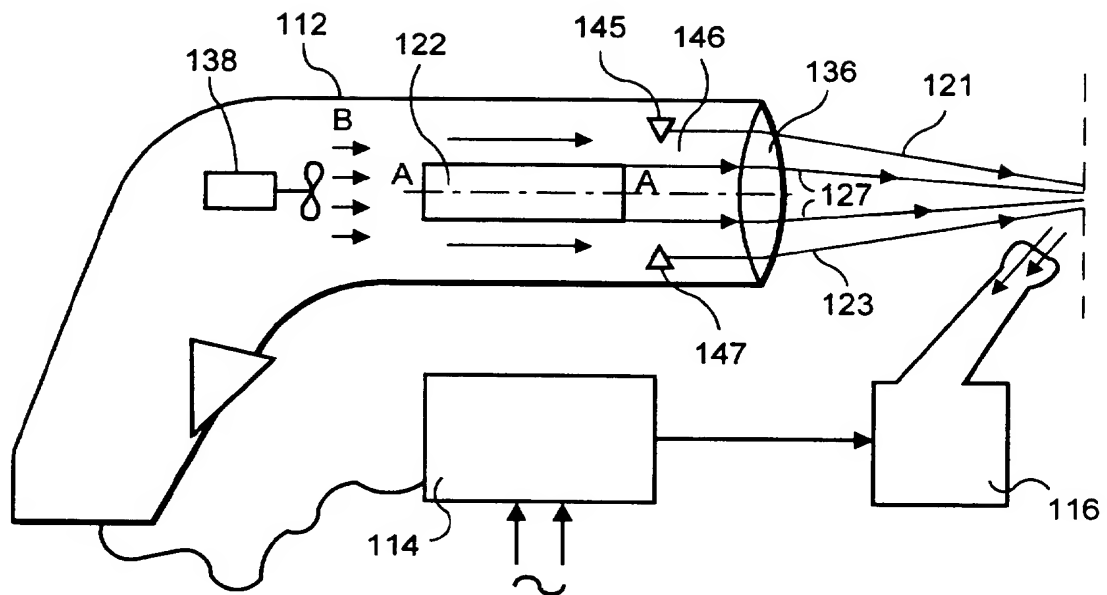


FIG. 5

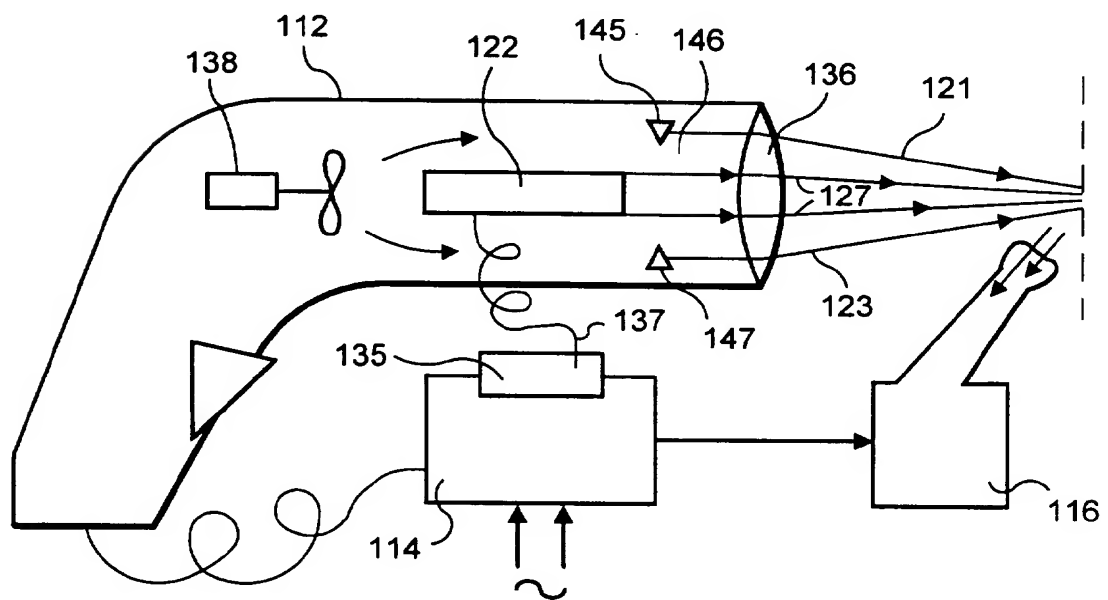


FIG. 6

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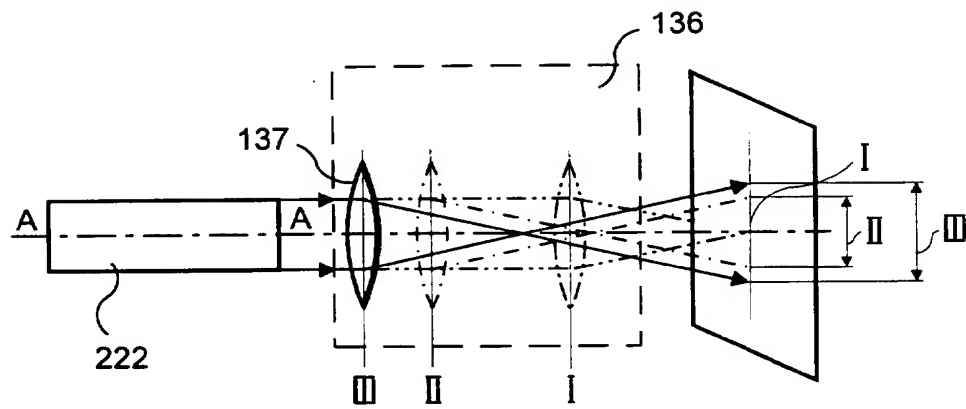


FIG. 7

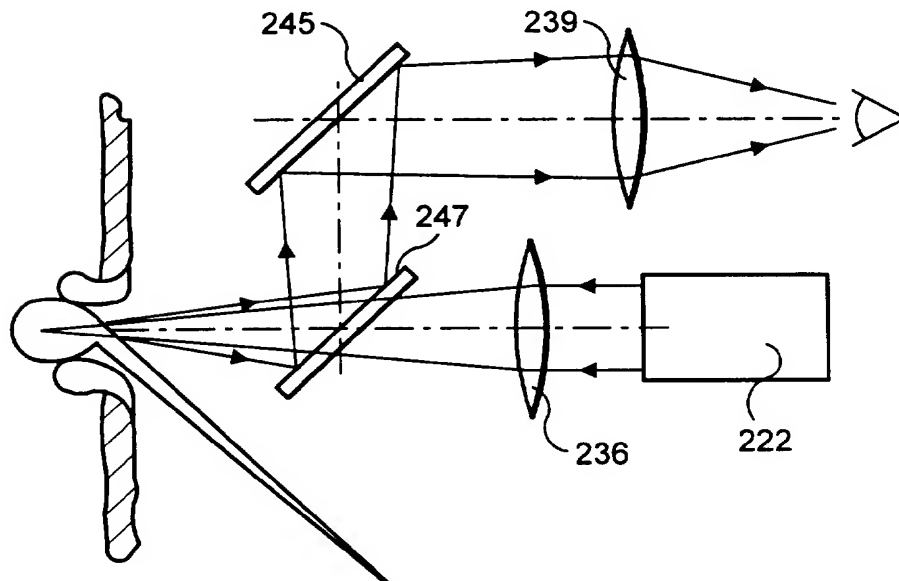
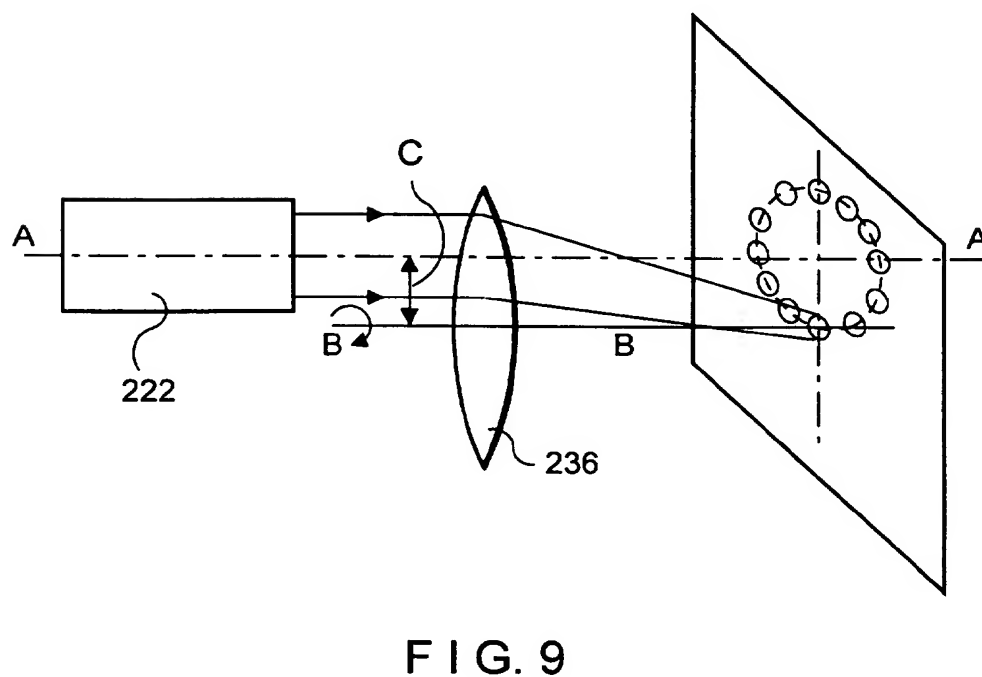
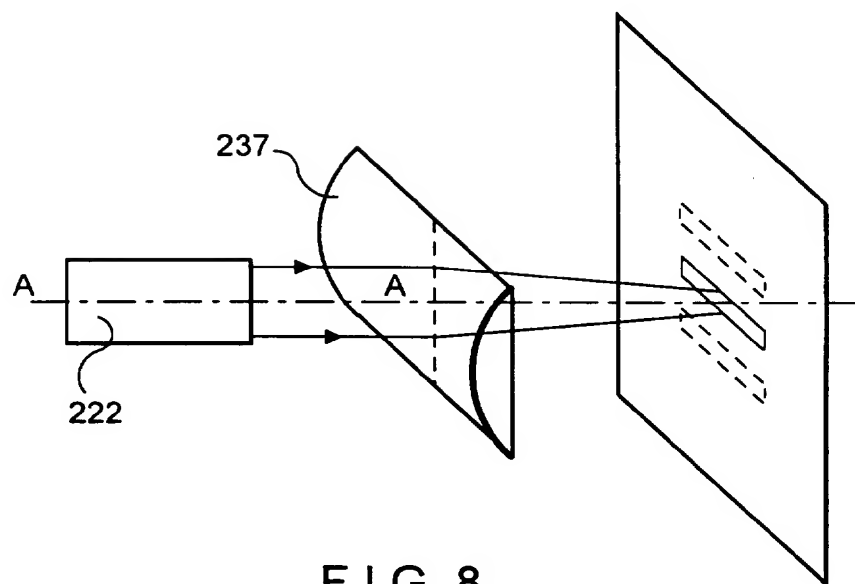


FIG. 10

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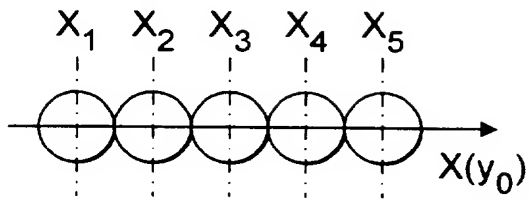


FIG. 11

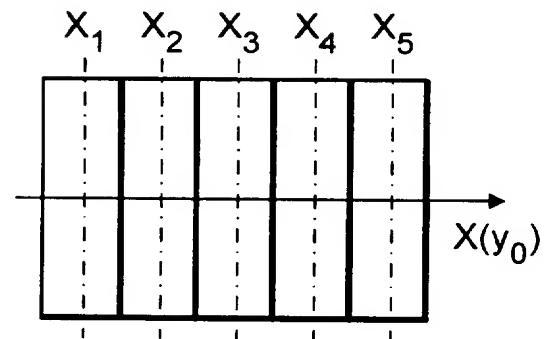


FIG. 12

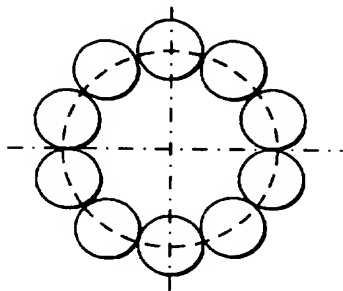


FIG. 13

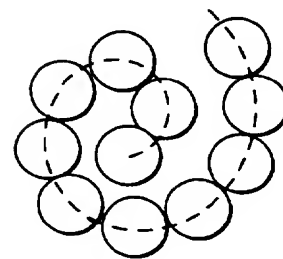


FIG. 14

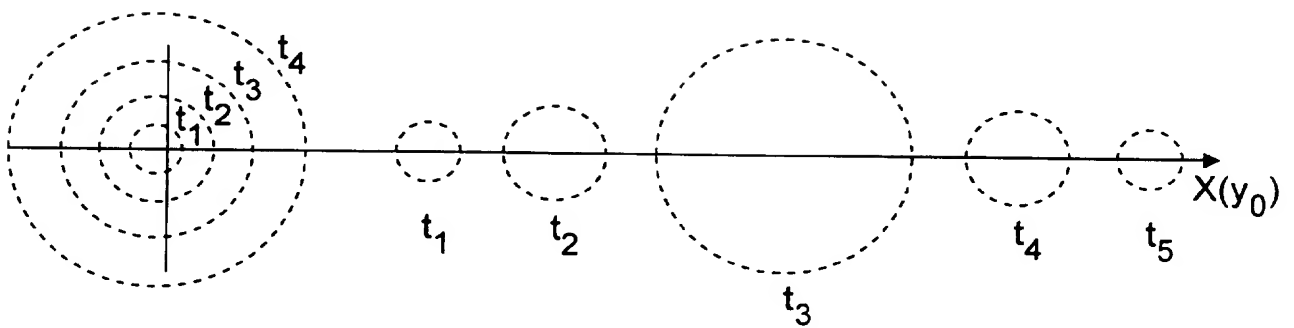


FIG. 15

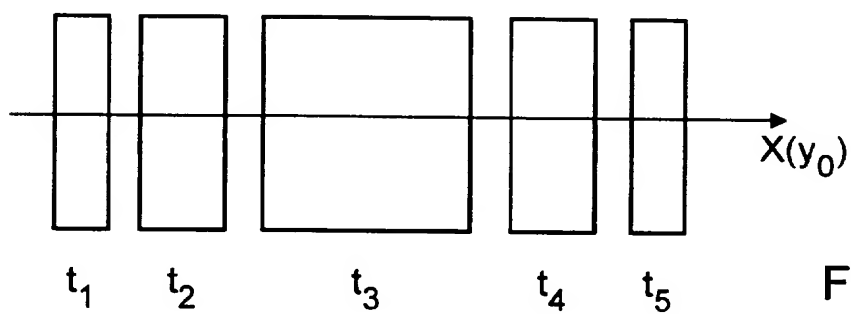


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/02984

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/06

US CL :606/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/3-18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,950,266 (SINOFSKY) 21 August 1990, see entire document.	1-20
Y	US, A, 5,192,278 (HAYES ET AL.) 09 March 1993, see entire document.	1-20

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

13 JUNE 1996

Date of mailing of the international search report

01 JUL 1996

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DAVID SHAY

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Search result: 1 of 1

(WO/1996/036396) THERAPEUTIC DEVICE WITH A LASER IRRADIATOR

[Biblio. Data](#) [Description](#) [Claims](#) [National Phase](#) [Notices](#) [Documents](#)

Latest bibliographic data on file with the International Bureau



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Applicant: WILDEN, Lutz [DE/DE]; (DE).
 Inventor: WILDEN, Lutz; (DE).
 Agent: WINTER, BRANDL ET AL PARTNERSCHAFT; Alois-Steinecker-Strasse 22, D-85354 Freising (DE).

Priority Data: 295 08 077.9 16.05.1995 DE
 295 08 844.3 29.05.1995 DE
 295 15 096.3 20.09.1995 DE
 295 19 481.2 08.12.1995 DE
 295 19 482.0 08.12.1995 DE
 295 20 581.4 27.12.1995 DE

Title: (EN) THERAPEUTIC DEVICE WITH A LASER IRRADIATOR
 (DE) THERAPIEGERÄT MIT EINER LASERBESTRAHLUNGSVORRICHTUNG

Abstract: (EN) The present invention relates in general to therapeutic devices with a laser irradiator. It relates especially to an oral care device, a device for treating rhinitis and acne, a device for stimulating testosterone, an inner ear trouble treatment device for treating chronic complex inner ear problems, a device for stimulating the central nervous system, a device for the treatment and prevention of bedsores and a device for the bio-stimulation of plants.
 (DE) Die vorliegende Erfindung bezieht sich allgemein auf Therapiegeräte mit einer Laserbestrahlungsvorrichtung. Insbesondere bezieht sich die Erfindung auf ein Mundpflegegerät, ein Gerät zur Therapie von Rhinitis und Akne, ein Gerät zur Stimulation von Testosteron, ein Innenohrstörungs-Behandlungsgerät zur Therapie einer chronischen komplexen Innenohrstörung, ein Gerät zur Stimulierung des Zentralnervensystems, ein Gerät zur Therapie und Prophylaxe von Dekubitus sowie auf ein Gerät zur Biostimulation von Pflanzen.

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**INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE
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(21) Internationales Aktenzeichen: PCT/DE96/00789		(81) Bestimmungsstaaten: JP, US, europäisches Patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) Internationales Anmeldedatum: 6. Mai 1996 (06.05.96)			
(30) Prioritätsdaten:		Veröffentlicht <i>Ohne internationalen Recherchenbericht und erneut zu veröffentlichen nach Erhalt des Berichts.</i>	
295 08 077.9	16. Mai 1995 (16.05.95) DE		
295 08 844.3	29. Mai 1995 (29.05.95) DE		
295 15 096.3	20. September 1995 (20.09.95) DE		
295 19 481.2	8. December 1995 (08.12.95) DE		
295 19 482.0	8. December 1995 (08.12.95) DE		
295 20 581.4	27. December 1995 (27.12.95) DE		
(71)(72) Anmelder und Erfinder: WILDEN, Lutz [DE/DE]; Hofäckerweg 16a, D-94051 Hauzenberg (DE).			
(74) Anwalt: KUHNEN, WACKER & PARTNER; Alois- Steinecker-Strasse 22, D-85354 Freising (DE).			

(54) Title: THERAPEUTIC DEVICE WITH A LASER IRRADIATOR

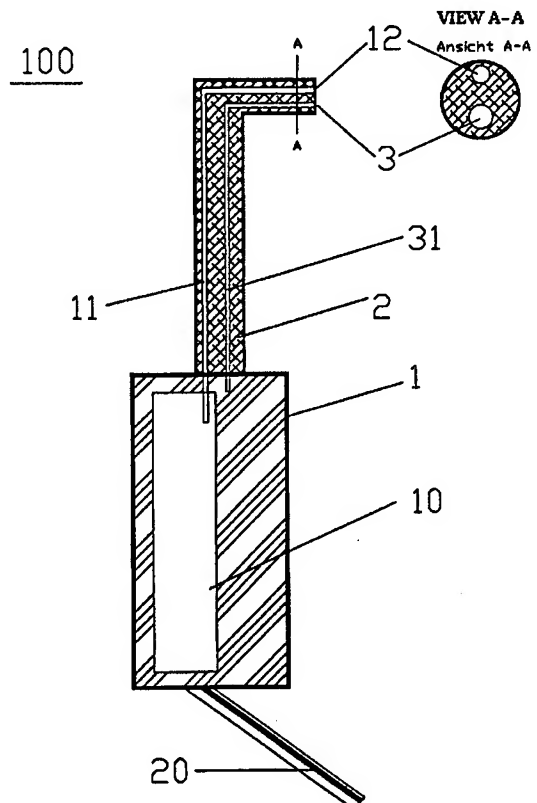
(54) Bezeichnung: THERAPIEGERÄT MIT EINER LASERBESTRAHLUNGSVORRICHTUNG

(57) Abstract

The present invention relates in general to therapeutic devices with a laser irradiator. It relates especially to an oral care device, a device for treating rhinitis and acne, a device for stimulating testosterone, an inner ear trouble treatment device for treating chronic complex inner ear problems, a device for stimulating the central nervous system, a device for the treatment and prevention of bedsores and a device for the bio-stimulation of plants.

(57) Zusammenfassung

Die vorliegende Erfindung bezieht sich allgemein auf Therapiegeräte mit einer Laserbestrahlungsvorrichtung. Insbesondere bezieht sich die Erfindung auf ein Mundpflegegerät, ein Gerät zur Therapie von Rhinitis und Akne, ein Gerät zur Stimulation von Testosteron, ein Innenohrstörungs-Behandlungsgerät zur Therapie einer chronischen komplexen Innenohrstörung, ein Gerät zur Stimulierung des Zentralnervensystems, ein Gerät zur Therapie und Prophylaxe von Dekubitus sowie auf ein Gerät zur Biostimulation von Pflanzen.



LEDIGLICH ZUR INFORMATION

Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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BeschreibungTherapiegerät mit einer Laserbestrahlungsvorrichtung

5 Die vorliegende Erfindung bezieht sich allgemein auf Therapiegeräte mit einer Laserbestrahlungsvorrichtung. Insbesondere bezieht sich die Erfindung auf ein Mundpfle-
10 gegerät gemäß dem Oberbegriff des Anspruchs 1, ein Gerät zur Therapie von Rhinitis und Akne gemäß dem Oberbegriff des Anspruchs 10, ein Gerät zur Stimulation von Testos-
15 teron im Hoden gemäß dem Oberbegriff des Anspruchs 14, ein Innenohrstörungs-Behandlungsgerät zur Therapie einer chronischen komplexen Innenohrstörung gemäß dem Oberbe-
griff des Anspruchs 19, ein Gerät zur Stimulierung des
20 Zentralnervensystems gemäß dem Oberbegriff des Anspruchs 25, ein Gerät zur Therapie und Prophylaxe von Dekubitus gemäß dem Oberbegriff des Anspruchs 33 sowie auf ein Ge-
rät zur Biostimulation von Pflanzen gemäß dem Oberbegriff des Anspruchs 42.

20 Bei den von der Erfindung weitergebildeten Mundpfle-
geräten handelt es sich vorzugsweise um solche Geräte,
die einen Handgriff aufweisen, der mit einem in den Mund
einführbaren Mundstück versehen ist, an dessen mundseiti-
25 gem Ende eine Mundpflegevorrichtung sitzt. Gemäß einer
Weiterbildung der Erfindung werden von dieser vorzugs-
weise solche Mundpflegevorrichtungen umfaßt, die elek-
trisch betrieben werden. Eine derartige elektrisch be-
triebene Mundpflegevorrichtung ist vorzugsweise eine
30 Munddusche oder auch eine elektrische Zahnbürste. Die
Vorteile derartig betriebener Mundpflegegeräte im Hin-
blick auf die Reinhaltung der Zähne und/oder die Massage
des Zahnfleisches sind hinlänglich bekannt und sollen da-
her an dieser Stelle nicht weiter diskutiert werden.

35 In Zahnarztpraxen werden in letzter Zeit vermehrt so-
genannte "Low-Level-Laserbestrahlungsvorrichtungen" ein-

gesetzt; ihr Verwendungszweck ist insbesondere die Therapie und Prophylaxe der Parodontose sowie die Therapie und die Prophylaxe von Stomatitis aphtosa, von Herpeserkrankungen der Lippen (Herpes labiales) und der Mundschleimhaut sowie von Akne. Der Zusatz "Low-Level" ("Niedrigpegel") für derartige therapeutische Laserbestrahlungsvorrichtungen wurde deshalb geprägt, weil die Ausgangsleistung bzw. Dosierung des abgegebenen Laserstrahls so bemessen ist, daß er keinerlei thermische Wirkung an dem beaufschlagten Körperteil, also insbesondere dem Zahnfleisch, hervorruft.

Es gibt bereits zahlreiche wissenschaftliche Veröffentlichungen, in denen untersucht wird, welche biologische bzw. therapeutische Wirkung kohärentes Licht geeigneter Wellenlänge auf lebendes Gewebe hat. In zahlreichen dieser Veröffentlichungen wird eine stimulierende Wirkung auf den zellulären Stoffwechsel beschrieben. Eine wesentliche Wirkung des kohärenten Lichts scheint insbesondere darin zu liegen, daß es die mitochondriale Adenosintriphosphat-Synthese ("ATP-Synthese") stimuliert. Zellschädigende Wirkungen von kohärentem Licht - sofern dessen Intensität bzw. Energiegehalt nicht zu hoch gewählt wird - sind demgegenüber noch nicht beobachtet worden, so daß das lebende Gewebe durch eine solche therapeutische Bestrahlung offensichtlich nicht geschädigt werden kann.

Trotz der anerkannt guten therapeutischen Wirksamkeit einer derartigen Low-Level-Laserbestrahlungsvorrichtung sind ihrer weiteren Verbreitung bei der Zahnfleischbehandlung dadurch Grenzen gesetzt, daß bislang lediglich in Zahnarztpraxen entsprechende Geräte zur Verfügung stehen. Die jeweilige Therapie kann daher nur vom Zahnarzt durchgeführt werden. Da die zu erzielende therapeutische Wirksamkeit in vielen Fällen eine relativ lange Behandlungsdauer erfordert, ist der Einsatz solcher Low-Level-

Laserbestrahlungsvorrichtungen für die meisten Patienten vergleichsweise beschwerlich, so daß ihrer weiteren Verbreitung auch insofern Grenzen gesetzt sind.

5 Der Erfindung liegt die Aufgabe zugrunde, ein Mundpflegegerät gemäß dem Oberbegriff des Anspruchs 1 zu schaffen, mit dem therapeutische Wirkungen erzielbar sind.

10 Diese Aufgabe wird erfindungsgemäß mit der im Kennzeichnungsteil des Anspruchs 1 angegebenen Maßnahme gelöst.

15 Der Kerngedanke der vorliegenden Erfindung ist somit in einer Kombination eines herkömmlichen Mundpflegegeräts gemäß dem Oberbegriff des Anspruchs 1 mit einer Low-Level-Laserbestrahlungsvorrichtung zu sehen, wobei diese Low-Level-Laserbestrahlungsvorrichtung so im Mundpflegegerät angeordnet ist, daß der von ihr erzeugte Laserstrahl über das Mundstück in den Mund projiziert werden
20 kann. Das erfindungsgemäße Mundpflegegerät stellt somit ein Kombinationsgerät dar, das neben der üblichen Mundpflege auch die therapeutische Behandlung des Zahnfleisches und dergleichen ermöglicht. Ein derartiges Kombinationsgerät kann sowohl derart gestaltet sein, daß eine
25 erfindungsgemäße Low-Level-Laserbestrahlungsvorrichtung fest in einem herkömmlichen Mundpflegegerät untergebracht ist, als auch so, daß die Low-Level-Laserbestrahlungsvorrichtung (beispielsweise in Form eines Laserstifts) lösbar am Mundpflegegerät befestigbar ist.
30

35 Neben dem unbestreitbaren Vorteil, daß mit dem erfindungsgemäßen Kombinationsgerät langwierige Besuche beim Zahnarzt vermieden werden können, hat dies den weiteren Vorteil, daß die therapeutische Behandlung wesentlich öfter und auch gleichmäßiger erfolgen kann, so daß zu er-

warten ist, daß die Wirksamkeit gegenüber den in den Zahnarztpraxen installierten Laserbestrahlungsvorrichtungen gegebenenfalls sogar verbessert werden kann. Durch die häufige Anwendung des erfindungsgemäßen Mundpflegegeräts sind gute therapeutische Wirkungen selbst dann zu erwarten, wenn aus Sicherheitsgründen für den Laserstrahl eine geringe Ausgangsleistung von beispielsweise lediglich 1 bis 5 mW gewählt wird (Laserklasse IIIA).

10 Die erfindungsgemäß vorgesehene Low-Level-Laserbestrahlungsvorrichtung kann beispielsweise im Handgriff des Mundpflegegeräts untergebracht werden, wobei der von ihr erzeugte Laserstrahl über eine Lichtleitervorrichtung durch das Mundstück hindurchgeleitet wird und über eine
15 am mundseitigen Ende des Mundstücks vorgesehene Linse aus diesem austritt. Da zur Erzeugung des Laserstrahls vorzugsweise ein kompakter Diodenlaser verwendet wird, werden somit die Gesamtabmessungen des Mundpflegegeräts gegenüber einem herkömmlichen Gerät kaum nennenswert vergrößert, zumal die elektrische Energieversorgung über die
20 ohnehin vorhandene Versorgung der im Mundpflegegerät installierten Mundpflegevorrichtung, wie beispielsweise einer Munddusche oder einer elektrischen Zahnbürste, erfolgen kann. Im Falle einer als Laser-Beistellstift ausgebildeten Laserbestrahlungsvorrichtung kann die Energieversorgung über eine gemeinsame Aufladestation beispielsweise in Form einer Akku-Standkonsole erfolgen.

Die den Laserstrahl projizierende Linse ist am mundseitigen Ende des Mundstücks vorzugsweise so angeordnet,
30 daß der Laserstrahl beim Gebrauch des Geräts im wesentlichen auf das Zahnfleisch gerichtet ist. Da die Stellung des Mundstücks beim Gebrauch einer Munddusche oder einer elektrischen Zahnbürste weitgehend definiert ist, bereitet die Auswahl einer hierfür geeigneten Position der
35 Linse in der Praxis keine Probleme. Um auf jeden Fall si-

cherzustellen, daß weite Bereiche des Zahnfleisches vom Laserstrahl beaufschlagt werden, könnte gegebenenfalls daran gedacht werden, den Laserstrahl über mehrere Linsen abzustrahlen und/oder eine Linse mit breiter Fächerung zu
5 verwenden.

Das erfindungsgemäße Mundpflegegerät wird bestimmungsgemäß insbesondere von Laien verwendet. Eine unsachgemäße Handhabung des Mundpflegegeräts kann daher insbesondere dann zu Problemen führen, wenn die Ausgangsleistung des Laserstrahls beispielsweise über 5 mW liegt und die betreffende Person den Laserstrahl auf besonders empfindliche Körperteile wie beispielsweise das Auge richtet. Um solche Gefahren auszuschließen, kann entweder
10 daran gedacht werden, die Ausgangsleistung von vornherein auf ungefährliche Werte zu begrenzen, oder aber einen Sensor vorzusehen, der jeweils erfaßt, ob sich das mundseitige Ende des Mundstücks bzw. die Linse im Mund befindet oder nicht; wenn der Sensor erkennt, daß dies nicht
15 der Fall ist, wird die Low-Level-Laserbestrahlungsvorrichtung von einer entsprechenden Steuervorrichtung automatisch abgeschaltet, so daß außerhalb der Mundhöhle befindliche Körperteile keinesfalls gefährdet werden können.
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Die akute oder chronische sowie die allergische Rhinitis zählt zu den am häufigsten auftretenden und gleichzeitig zu den als sehr unangenehm empfundenen Erkrankungen der Nasenschleimhäute. Wenn keine Maßnahmen zur Behandlung ergriffen werden, so ist der Schnupfen zumindest mit einem sehr starken Verbrauch von Taschentüchern verbunden, was sowohl kostenträchtig als auch unhygienisch ist. Die bislang bekannten Behandlungsmethoden in Form der Verabreichung von Medikamenten oder dergleichen haben
30 andererseits den Nachteil, daß die damit einhergehenden Nebenwirkungen wie das übermäßige Austrocknen der
35

Schleimhäute vom medizinischen Standpunkt sehr bedenklich sind, so daß vielfach vom Gebrauch solcher Medikamente abgeraten wird.

5 In den Praxen von HNO-Ärzten stehen zwar bereits Geräte zur Verfügung, die in der Lage sind, durch Inhalation, Wärmebehandlung usw. eine vergleichsweise gute Heilung von Schnupfen oder Katarrh herbeizuführen, jedoch ist hierfür stets ein Besuch beim Arzt erforderlich, was
10 entsprechend zeitaufwendig und lästig ist.

Es wäre daher wünschenswert, ein einfach handzuhabendes und gleichwohl wirksames Gerät zur Verfügung zu haben, das in der Lage ist, akute oder chronische Rhinitis
15 wirksam zu behandeln oder sogar völlig auszuheilen.

Ein weiterer wesentlicher Gesichtspunkt der vorliegenden Erfindung liegt somit darin, ein Gerät zur Therapie und Prophylaxe von akuter oder chronischer Rhinitis
20 zu schaffen, das eine einfache und gleichwohl wirksame therapeutische Behandlung von Rhinitis gestattet.

Die vorliegende Erfindung beruht auf der Erkenntnis, daß die an sich bekannte, einleitend erläuterte zellstoffwechselstimulierende Wirkung von kohärentem Licht
25 geeigneter Energie und geeigneter Wellenlänge gegebenenfalls auch beim Auftreten von Rhinitis eine positive bzw. regenerierende und anregende biologische Wirkung entfalten könnte. Untersuchungen des Anmelders haben tatsächlich
30 ergeben, daß durch Anwendung von kohärentem Licht beachtliche positive Auswirkungen bei der Therapie und Prophylaxe von Rhinitis festgestellt werden können. Die genannten biologischen Wirkungen des Laserlichts ermöglichen darüber hinaus auch eine positive Beeinflussung von
35 Aknepusteln oder anderen kleinflächigen kosmetisch störenden entzündlichen Hautveränderungen oder Narben. Dies

gilt in gleicher Weise für die Stimulation von Testosteron.

Unter Zugrundelegung dieser wissenschaftlichen Erkenntnis schlägt die Erfindung somit ein Gerät zur Therapie und Prophylaxe von Rhinitis sowie von Akne vor, das eine in einem Einhandgehäuse befindliche Low-Level-Laserbestrahlungsvorrichtung aufweist, die mindestens einen Laserstrahl erzeugt, der über eine in die Nasenöffnung eines Patienten einführbare Lichtleitervorrichtung auf das Naseninnere einwirkt bzw. auf Aknepustel gerichtet werden kann. Die Erfindung schafft somit ein sehr einfach und insbesondere ohne Hilfe eines Arztes oder Therapeuten bedienbares Gerät, das in jedem Haushalt vorhanden sein kann oder ggf. sogar unterwegs mitgeführt werden kann, so daß eine vergleichsweise konstante und entsprechend wirksame Behandlung durchgeführt werden kann. Insbesondere sind zeitaufwendige und teure Besuche beim HNO-Arzt oder anderen Ärzten entbehrlich.

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Wie bereits erwähnt wurde, werden die von der Erfindung verwendeten Low-Level-Laserbestrahlungsvorrichtungen bereits in zahlreichen Arztpraxen zur Behandlung von erkranktem Gewebe eingesetzt. Low-Level-Laserbestrahlungsvorrichtungen stellen somit ein bewährtes Behandlungsinstrument dar, so daß das erfindungsgemäße Gerät auf die hiermit gewonnenen Erfahrungen zurückgreifen kann, was dazu führt, daß das erfindungsgemäße Gerät trotz äußerst geringem Aufwand mit sehr hoher Zuverlässigkeit ausgestattet werden kann; insbesondere ist es möglich, die Herstellungs- und Entwicklungskosten in vergleichsweise niedrigen Grenzen zu halten.

Der sogenannte Tinnitus stellt eine chronische komplexe Innenohrstörung dar. Es handelt sich hierbei um eine Erkrankung der Hörschnecke (Cochlea). Der sogenannte

chronische vestibuläre Vertigo stellt demgegenüber eine Erkrankung des Vestibularorgans (des Labyrinths) des Ohres dar. Beide Erkrankungen sind häufige Störungen des Innenohres und werden mit dem erfindungsgemäß Gerät vorzugsweise behandelt; jedoch können mit diesem Gerät ggf. auch weitere, hier nicht näher erläuterte Erkrankungen des Innenohres behandelt werden, wie z.B. die Innenohrschwerhörigkeit.

10 Für die betroffene Person äußert sich der Tinnitus als permanenter Pfeifton bzw. als ein ununterbrochenes Summgeräusch in bestimmten Frequenzen. Dieser permanente Pfeifton ist für die betroffene Person einerseits äußerst unangenehm und kann sogar zu psychischen Störungen führen, während andererseits das Hörvermögen in dem zugeordneten Frequenzbereich entsprechend eingeschränkt ist. Aus diesem Grund werden in letzter Zeit vermehrt Anstrengungen unternommen, den Tinnitus geeigneten Therapien zu unterziehen.

20 Als eine der erfolgreichsten Therapien zur Tinnitusbehandlung hat sich in letzter Zeit ebenfalls die Verwendung eines Low-Level-Lasers herauskristallisiert. Im Falle der Tinnitusbehandlung mittels eines derartigen Low-Level-Lasers wurden insbesondere bei der Bestrahlung über das Mastoid (an einer ca. 2 cm hinter der Ohrmuschel befindlichen Stelle) oder des Gehörgangs bereits beachtliche Heilungserfolge erzielt. Auch der Vertigo und die Innenohrschwerhörigkeit können mit dieser Methode behandelt werden.

35 Die genannten Low-Level-Laservorrichtungen sind Spezialgeräte, die derzeit nur in entsprechend eingerichteten Arztpraxen oder Kliniken vorhanden sind. Der betroffene Patient muß daher für jede Innenohrstörungs- bzw. Tinnitusbehandlung eine solche Arztpraxis bzw. Klinik

aufsuchen. Da eine fühlbare Heilungswirkung bei einer Low-Level-Laserbestrahlung in der Regel erst nach vergleichsweise langen Zeiträumen eintritt, muß der Patient entsprechend häufig die Arztpraxis bzw. Klinik aufsuchen.

5 Dies ist einerseits für den Patienten lästig und hat andererseits den Nachteil, daß entsprechend hohe Behandlungskosten auftreten.

Ein weiterer wesentlicher Gesichtspunkt der vorliegenden Erfindung liegt somit darin, ein Innenohrstörungs-

10 Behandlungsgerät zu schaffen, mit dem die Behandlungskosten deutlich herabgesetzt werden können.

Die Erfindung schlägt in diesem Zusammenhang vor, eine Low-Level-Laserbestrahlungsvorrichtung vorzusehen, die

15 mittels einer geeigneten Befestigungsvorrichtung lösbar derart am Ohr eines Patienten befestigt werden kann, daß der Laserstrahl auf mindestens einen vorbestimmten Bereich des Ohres einwirkt. Der Kerngedanke dieser Maßnahme ist somit darin zu sehen, eine Low-Level-Laserbestrahlungsvorrichtung zu schaffen, die der Patient für die

20 Dauer der Behandlung ständig mit sich trägt, so daß eine entsprechend intensive Behandlung erfolgt, was erwarten läßt, daß die Heilungsaussichten mit dem erfindungsgemä-

25 ßen Gerät sogar noch höher sind, als mit den in Arztpraxen bzw. Kliniken vorhandenen herkömmlichen Low-Level-Laserservorrichtungen. Ein weiterer Vorteil des erfindungsgemäßen Innenohrstörungs-Behandlungsgeräts liegt darin, daß es im Prinzip ausreicht, wenn das Gerät von einem ent-

30 sprechenden Therapeuten zu Beginn der Behandlung angepaßt wird; weitere Arztbesuche sind für den Patienten dann nicht mehr notwendig, so daß die Therapie für den Patienten entsprechend bequemer ist. Die mit den Arzt- bzw. Klinikbesuchen verbundenen Behandlungskosten entfallen

35 ebenfalls, so daß insgesamt große Kostenvorteile erzielt werden.

Die Low-Level-Laserbestrahlungsvorrichtung des erfindungsgemäßen Innenohrstörungs-Behandlungsgeräts kann in der Befestigungsvorrichtung selbst untergebracht sein, wobei in diesem Fall vorzugsweise eine Lichtleitervorrichtung vorgesehen ist, über die der von der Laserbestrahlungsvorrichtung abgegebene Laserstrahl ggf. einer Linse zugeführt wird, aus der der Laserstrahl austritt und auf den/die vorbestimmten Bereich(e) einwirkt. Der Lichtleiter besteht vorzugsweise aus einem Material, das es dem das Gerät anpassenden Therapeuten gestattet, die Position des Lichtaustritts, d.h. den vorbestimmten Wirkungsbereich, durch Verbiegen, Verschwenken oder dergleichen einzustellen. Gegebenenfalls kann zwischen der Befestigungsvorrichtung und der Lichtleitervorrichtung auch eine Verstellvorrichtung vorgesehen werden, die es gestattet, die Länge und/oder Richtung der Lichtleitervorrichtung durch Verschrauben oder dergleichen zu ändern.

Alternativ kann es sich bei der Low-Level-Laserbestrahlungsvorrichtung des erfindungsgemäßen Innenohrstörungs-Behandlungsgeräts auch um eine separate Einheit handeln, deren Laserstrahl über eine flexible Lichtleitervorrichtung ggf. einer an ihrem Ende sitzenden Linse zugeführt wird, wobei in diesem Fall lediglich die Linse und/oder das Ende der Lichtleitervorrichtung mittels der Befestigungsvorrichtung am Ohr befestigt wird. Bei dieser Variante der Erfindung wird die Laserbestrahlungsvorrichtung beispielsweise in die Hemdtasche, in die Hosentasche oder an den Gürtel des Patienten gesteckt. Diese Variante der Erfindung wird daher insbesondere dann eingesetzt, wenn die verwendete Low-Level-Laserbestrahlungsvorrichtung und/oder deren Batteriestromversorgung vergleichsweise groß und/oder schwer ist.

Ein weiterer, wesentlicher Aspekt bei diesem Gerät liegt darin, daß als Befestigungsvorrichtung eine bereits vorhandene Einrichtung verwendet wird. Bei einer solchen Einrichtung kann es sich insbesondere um ein Brillengestell, ein Hörgerät, einen Tinnitusmasker oder um ein Kombinationsgerät aus einem Tinnitusmasker und einem Hörgerät handeln (ein Tinnitusmasker ist ein kleiner Lautsprecher, der ein Geräusch in der Frequenz des Tinnitus erzeugt, so daß der Patient den Eindruck hat, beim Tinnitus würde es sich um ein externes Geräusch handeln). Selbstverständlich ist es jedoch auch möglich, für das erfindungsgemäße Innenohrstörungs-Behandlungsgerät eine eigene Befestigungsvorrichtung vorzusehen, wie beispielsweise einen am Ohr befestigbaren Bügel, ein in das Ohr einführbares Teil (vergleichbar einem Innenohr-Hörgerät) oder einen auf den Kopf aufstülpbaren Bügel nach Art eines Kopfhörers.

Störungen des Zentralnervensystems eines Menschen treten bekanntlich in mehr oder weniger gravierender Form auf. In diesem Zusammenhang ist insbesondere die bekannte Alzheimerkrankheit zu nennen. Viele Menschen sind darüber hinaus von einer allgemeinen oder spezifischen Hirnleistungsschwäche betroffen, leiden an Depressionen, Konzentrationsstörungen usw. Es wäre daher wünschenswert, ein einfach handzuhabendes und gleichwohl wirksames Gerät zur Verfügung zu haben, das durch geeignete Stimulierung des Zentralnervensystems die vorstehend genannten Erkrankungen wirksam behandeln oder sogar völlig ausschalten kann. Ein derartiges Gerät könnte gegebenenfalls sogar zur allgemeinen zerebralen Leistungssteigerung verwendet werden.

Ein weiterer wesentlicher Gesichtspunkt der vorliegenden Erfindung liegt somit darin, ein Gerät zur Stimulierung des Zentralnervensystems zu schaffen, das eine

einfache und gleichwohl wirksame therapeutische Behandlung zerebraler Erkrankungen gestattet.

Der vorliegende Aspekt der Erfindung beruht auf der
5 Erkenntnis, daß die bekannte zellstoffwechselstimulierende Wirkung von kohärentem Licht geeigneter Energie und geeigneter Wellenlänge gegebenenfalls auch im Zentralnervensystem eine positive bzw. regenerierende und anregende biologische Wirkung entfalten könnte. Untersuchungen des
10 Anmelders haben tatsächlich ergeben, daß durch Anwendung von kohärentem Licht beachtliche positive Auswirkungen auf das Zentralnervensystem festgestellt werden können. Es ist somit zu erwarten, daß die von der Erfindung vorgeschlagene Anwendung von kohärentem Licht zur Stimulierung des Zentralnervensystems geeignet ist, die eingangs
15 genannten Krankheiten, wie insbesondere die Alzheimerkrankheit, die allgemeine oder spezifische Hirnleistungsschwäche, Depressionen, Konzentrationsstörungen usw., therapeutisch wirksam zu behandeln oder sogar völlig aus-
20 zuschalten.

Unter Zugrundelegung dieser wissenschaftlichen Erkenntnis schlägt die Erfindung somit ein Gerät zur Stimulierung des Zentralnervensystems vor, das eine Low-Level-
25 Laserbestrahlungsvorrichtung aufweist, die mindestens einen Laserstrahl erzeugt, der auf mindestens einen vorbestimmten Bereich der Haut des Patienten, vorzugsweise in unmittelbarer Nähe des zu stimulierenden Zentralnervensystems, einwirkt. Aufgrund der bereits zahlreichen Verwen-
30 dung derartiger Low-Level-Laserbestrahlungsvorrichtungen (siehe die obigen Ausführungen) stellen diese ein bewährtes Behandlungsinstrument dar, so daß das erfindungsgemäße Gerät auf die hiermit gewonnenen Erfahrungen zurückgreifen kann, was dazu führt, daß das erfindungsgemäße
35 Gerät trotz äußerst geringem Aufwand mit sehr hoher Zuverlässigkeit ausgestattet werden kann; auch die Herstel-

lunungs- und Entwicklungskosten halten sich dadurch in vergleichsweise niedrigen Grenzen.

Ein weiterer Gesichtspunkt liegt darin, daß das Zentralnervensystem-Stimulierungsgerät in der Lage ist, verschiedene Bereiche des Zentralnervensystems entweder gleichzeitig oder - je nach Indikationsstellung - partiell mit dem Laserstrahl bzw. den Laserstrahlen der Low-Level-Laserbestrahlungsvorrichtung von außen zu behandeln. Dies kann beispielsweise dadurch erreicht werden, daß die Low-Level-Laserbestrahlungsvorrichtung auf den Kopf des Patienten einwirkt. Zu diesem Zweck ist es von besonderem Vorteil, wenn ein helm- oder haubenartiger Aufsatz für den Kopf des Patienten vorgesehen wird, wobei dieser Aufsatz vorzugsweise eine Vielzahl von Laserstrahl-Sendeelementen trägt, deren Laserstrahlen ins Innere des Aufsatzes gerichtet sind. Hierdurch ist es möglich, das Zentralnervensystem relativ gleichmäßig von außen zu behandeln; gleichwohl kann auf sehr einfache Weise eine gezielte bereichsweise Behandlung erfolgen, indem die entsprechenden Sendeelemente selektiv aktiviert werden.

Der Aufsatz kann beispielsweise an einem schwenkbaren Halter befestigt werden, so daß er auf einfache Weise nach Art einer Trockenhaube über den Kopf des Patienten gestülpt werden kann, wobei auch der Abstand der Sendeelemente zur Kopfhaut des Patienten äußerst einfach eingestellt werden kann. Zur Einstellung eines definierten Abstands zur Kopfhaut können alternativ oder zusätzlich zu dieser Maßnahme im Inneren des Aufsatzes Abstandshalter vorgesehen werden, die die Innenwand des Aufsatzes und damit die Laserstrahl-Sendeelemente in einem vorbestimmten Abstand zur Kopfhaut des Patienten halten. Derartige Abstandshalter sind insbesondere dann nützlich,

wenn der erfindungsgemäße Aufsatz ohne Halter aufgestülpt wird, d.h. eine Art Helm darstellt.

Die Laserstrahl-Sendeelemente können beispielsweise
5 jeweils aus einer Laserdiode gebildet werden, die entweder jeweils von einer eigenen Batterie oder aber von einer zentralen Stromversorgungseinrichtung gespeist werden. Alternativ hierzu kann jedes Laserstrahl-Sendeelement aus einer Lichtleitervorrichtung bestehen, an deren
10 Ende gegebenenfalls eine Linse sitzt. Am anderen Ende werden alle Laserstrahl-Sendeelemente beispielsweise aus einer gemeinsamen Laserlichtquelle gespeist. Alternativ hierzu kann für jedes oder zumindest für einen Teil der Laserstrahl-Sendeelemente eine eigene Laserlichtquelle
15 vorgesehen werden, so daß die Möglichkeit besteht, einige oder alle Laserstrahl-Sendeelementen mit anderer Frequenz und/oder Leistung zu betreiben. Die Laserlichtquellen können entweder Teil der Haube sein oder in einem externen Gerät angeordnet werden.

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Obgleich der genannte helm- oder haubenartige Aufsatz die bevorzugte Art der therapeutischen Behandlung des Kopfs eines Patienten darstellt, kann die Low-Level-Laserbestrahlungsvorrichtung auch auf jede andere Art auf
25 die zu beaufschlagenden Bereiche des Zentralnervensystems einwirken. So ist es zum Beispiel möglich, die Low-Level-Laserbestrahlungsvorrichtung an Schwenkarmen, Fühlern, externen Strahlern oder dergleichen anzubringen. Gegebenenfalls ist es sogar möglich, die Low-Level-Laserbestrahlungsvorrichtung als Teil eines Ganzkörperbehandlungsgeräts nach Art einer Sonnenbank auszubilden. In jedem Fall sollten jedoch Maßnahmen ergriffen werden, die sicher verhindern, daß die Intensität der abgegebenen Laserstrahlen nur so hoch ist, daß empfindliche Körperteile
30 wie insbesondere das Auge hierdurch nicht geschädigt werden.
35

Das von der Erfindung geschaffene Gerät zur Stimulierung des Zentralnervensystems kann sowohl als therapeutisches (medizinisch-technisches) Gerät als auch als solches Gerät konzipiert sein, das vom Laien in Eigenverantwortung benutzt wird. Ferner ist es möglich, ein solches Gerät als Münzgerät auszubilden, das bei Einwurf eines geeigneten Münzbetrages eine vorbestimmte Zeit arbeitet.

Es ist allgemein bekannt, daß bei längerer Bettlägrigkeit (wie beispielsweise im Altenheim, nach längerem Krankenhausaufenthalt oder bei ambulanter Pflege) das Problem des Wundliegens auftritt; dieses in Fachkreisen als Dekubitus bezeichnete Phänomen stellt eine ernsthafte Erkrankung der betroffenen Körperbereiche dar und bedarf daher einer sorgfältigen Behandlung. Gleichwohl hat es sich bislang als schwierig erwiesen, den Dekubitus geeignet zu behandeln; auch eine Vorbeugung oder Prophylaxe war bisher kaum möglich.

Es wäre daher wünschenswert, ein einfach handzuhabendes und gleichwohl wirksames Gerät zur Verfügung zu haben, das durch geeignete Stimulierung dem Auftreten von Dekubitus vorbeugen oder diesen nach seinem Auftreten wirksam behandeln oder sogar völlig ausschalten kann.

Ein weiterer wesentlicher Gesichtspunkt der vorliegenden Erfindung liegt somit darin, ein Gerät zur Therapie und Prophylaxe von Dekubitus zu schaffen, das eine einfache und gleichwohl wirksame therapeutische Behandlung von Dekubitus gestattet.

Die vorliegende Erfindung macht sich erneut die Erkenntnis zunutze, daß die an sich bekannte zellstoffwechselstimulierende Wirkung von kohärentem Licht geeigneter Energie und geeigneter Wellenlänge gegebenenfalls auch

beim Auftreten von Dekubitus eine positive bzw. regenerierende und anregende biologische Wirkung entfalten könnte. Untersuchungen des Anmelders haben tatsächlich ergeben, daß durch Anwendung von kohärentem Licht beachtliche positive Auswirkungen bei der Therapie und Prophylaxe von Dekubitus festgestellt werden können.

Unter Zugrundelegung dieser wissenschaftlichen Erkenntnis schlägt die Erfindung somit ein Gerät zur Therapie und Prophylaxe von Dekubitus vor, das eine Low-Level-Laserbestrahlungsvorrichtung aufweist, die mindestens einen Laserstrahl erzeugt, der auf bestimmte Bereich der Haut eines Patienten einwirkt.

Besonders vorteilhaft läßt sich das erfindungsgemäße Gerät dann einsetzen, wenn eine Vielzahl von Laserstrahl-Sendeelementen vorgesehen werden, die sich entsprechend auf verschiedene Bereiche der Haut des Patienten richten lassen, so daß eine gleichmäßige Behandlung der gesamten betroffenen Hautoberfläche möglich ist. Weiterhin ist es von Vorteil, eine Zeitschaltuhr vorzusehen, die nach Ablauf einer vorwählbaren Zeitspanne die Laserstrahl-Sendeelemente deaktiviert. Auf diese Weise kann jeder Patient einer vorbestimmten Behandlungsdauer von beispielsweise 30 Minuten unterzogen werden, ohne daß Pflegepersonal anwesend sein muß.

Um zu erreichen, daß die der Dekubitus-Therapie zu unterziehenden Hautbereiche gleichmäßig mit den Laserstrahlen beaufschlagt werden, ist es möglich, eine Streulinse zur Fächerung des Laserstrahls zu verwenden. Alternativ hierzu oder zusätzlich kann daran gedacht werden, den Abstrahlwinkel der Laserstrahl-Sendeelemente motorisch in der Weise zyklisch zu verändern, daß der wunde Bereich der Haut des Patienten in zyklischer Folge mit den Laserstrahlen beaufschlagt wird.

Dieses Gerät kann insbesondere auch zur Heimbehandlung (also zur Selbstbehandlung durch den Patienten) von chronischen Hauterkrankungen (Hauttherapie) sowie zur
5 Thymusstimulation verwendet werden.

Sowohl bei in Wohnungen verwendeten Zierpflanzen als auch beim gewerblichen Züchten von Pflanzen ist es oberstes Ziel, das Wachstum der betreffenden Pflanzen so weit
10 wie möglich zu fördern. Weiterhin soll die Widerstandskraft der Pflanzen gegenüber Erkrankungen oder Schädlingen erhöht werden. In aller Regel werden diese Ziele chemische Düngemittel und/oder durch chemische Pflanzenschutzmittel erreicht. Die Nachteile der Verabreichung
15 solcher Mittel sind hinlänglich bekannt und bedürfen somit keiner weiteren Erläuterung. Um den Einsatz derartiger chemischer Mittel zu verhindern oder doch zumindest zu reduzieren wurde daher bereits überlegt, das Pflanzenwachstum auf alternative Weise zu fördern, so beispielsweise
20 durch biologische Stimulierung. Bislang sind gleichwohl noch keine Geräte bekannt geworden, die eine zuverlässige biologische Stimulierung von Pflanzen ermöglichen.

25 Ein weiterer wesentlicher Gesichtspunkt der vorliegenden Erfindung liegt somit darin, ein Gerät zur Biostimulierung von Pflanzen zu schaffen, das eine einfache und gleichwohl wirksame Biostimulierung von Pflanzen gestattet.

30

Erfindungsgemäß wurde erstmals erkannt, daß die zellstoffwechselstimulierende Wirkung von kohärentem Licht geeigneter Energie und geeigneter Wellenlänge gegebenenfalls auch im Zellsystem von Pflanzen eine positive
35 bzw. regenerierende und anregende biologische Wirkung entfalten kann. Untersuchungen des Anmelders haben tat-

sächlich ergeben, daß durch Anwendung von kohärentem Licht beachtliche positive Auswirkungen auf das Zellsystem von Pflanzen festgestellt werden können. Es ist somit zu erwarten, daß die von der Erfindung vorgeschlagene Anwendung von kohärentem Licht zur Biostimulierung von Pflanzen geeignet ist, das Wachstum der betreffenden Pflanzen stark zu fördern und auch die Widerstandskraft der Pflanzen gegenüber Erkrankungen oder Schädlingen zu erhöhen.

10

Unter Zugrundelegung dieser wissenschaftlichen Erkenntnis schlägt die Erfindung somit ein Gerät zur Biostimulierung von Pflanzen vor, das eine Low-Level-Laserbestrahlungsvorrichtung aufweist, die mindestens einen Laserstrahl erzeugt, der auf bestimmte Bereiche der Oberfläche der Pflanzen einwirkt. Das erfindungsgemäße Gerät kann wirksam sowohl für Zierpflanzen oder dergleichen als auch für gewerbliche Zwecke wie beispielsweise in Gewächshäusern eingesetzt werden. Jedenfalls können chemische Mittel in erheblichen Mengen eingespart werden, wobei gleichwohl eine gute Wachstumsstimulierung und hohe Widerstandskraft gegen Erkrankungen erzielbar ist.

Besonders vorteilhaft läßt sich das erfindungsgemäße Gerät dann einsetzen, wenn eine Vielzahl von Laserstrahl-Sendeelementen vorgesehen werden, die sich entsprechend auf verschiedene Bereiche der zu stimulierenden Pflanze(n) richten lassen, so daß eine gleichmäßige Behandlung der gesamten Oberfläche der Pflanze(n) möglich ist. Weiterhin ist es von Vorteil, eine manuell bedienbare oder automatisch arbeitende Steuereinrichtung vorzusehen, die in Abhängigkeit von der Wachstumsphase der betreffenden Pflanze(n) eines oder mehrere Laserstrahl-Sendeelemente mit jeweils geeigneter Wellenlänge aktiviert und/oder deren Ausgangsleistung ändert. Somit ist eine

optimale Anpassung des erfindungsgemäßen Geräts an das Wachstum der Pflanze(n) möglich.

5 Untersuchungen haben gezeigt, daß mit den erfindungs-
gemäßen Geräten insbesondere dann große Erfolge erzielbar
sind, wenn die Low-Level-Laserbestrahlungsvorrichtung ei-
nen Laserstrahl mit einer Wellenlänge erzeugt, die sich
vom Ultraviolettbereich bis hin zum nahen Infrarotbereich
10 erstreckt, also von circa 180 nm bis etwa 1000 nm, wobei
die Ausgangsleistung bei den zur Eigenbehandlung vorgese-
henen Geräten vorzugsweise zwischen 1 mW und 5 mW liegen
sollte; das Gerät entspricht somit vorzugsweise der La-
serspezifikation Klasse IIIA. Wenn die Geräte demgegen-
über für den professionellen Gebrauch durch geschulte
15 Therapeuten bestimmt sind, werden Laserbestrahlungsvor-
richtungen mit Ausgangsleistungen bis maximal 500 mW ein-
gesetzt.

Gegebenenfalls kann daran gedacht werden, das Gerät
20 mit einer Hand-Einstellvorrichtung zu versehen, mittels
der die Ausgangsleistung der Low-Level-Laserbestrahlungs-
vorrichtung und/oder die Wellenlänge des Laserstrahls vom
Patienten auf einen wählbaren Wert eingestellt werden
kann. Die Low-Level-Laserbestrahlungsvorrichtung kann
25 entweder im kontinuierlichen Betrieb oder auch im pulsie-
renden Betrieb arbeiten, wobei die gewünschte Arbeits-
weise gegebenenfalls mit einem entsprechenden Wählschal-
ter eingestellt werden kann.

30 Die Erfindung wird nachstehend anhand der Beschrei-
bung von Ausführungsbeispielen unter Bezugnahme auf die
Zeichnung näher erläutert. Es zeigen:

Fig.1 eine Ausführungsform des Mundpflege-
35 räts;

Fig.2 eine Ausführungsform des Gerät (200) zur Therapie von Rhinitis und Akne, das auch zur Stimulation von Testosteron im Hoden eingesetzt werden kann;

Fig.3A und 3B zwei Ausführungsformen eines
5 Innenohrstörungs-Behandlungsgeräts zur Therapie einer chronischen komplexen Innenohrstörung;

Fig.4A und 4B zwei Ausführungsformen eines Geräts zur Stimulierung des Zentralnervensystems eines Patienten;

10 Fig.5 eine Ausführungsform eines Geräts zur Therapie und Prophylaxe von Dekubitus; und

Fig.6A und 6B zwei Ausführungsformen eines Geräts zur Biostimulation von Pflanzen.

15 In Fig.1 ist schematisch ein Mundpflegegerät in Form einer Munddusche 100 gezeigt. Diese Munddusche 100 weist einen Handgriff 1 auf, an dessen einem Ende ein rohrförmiges Mundstück 2 sitzt, während an seinem anderen Ende eine vorzugsweise flexible Versorgungsleitung 20 vorgesehen ist, die sowohl zur Wasserzufuhr als auch zur Stromversorgung dient. Die (nicht gezeigte) Pumpe der Munddusche kann sowohl in einem (nicht gezeigten) Wasserbehälter als auch im Handgriff 1 angeordnet sein. Der Ein/Aus-Schalter der Munddusche 100 kann ebenfalls entweder am
20 Wasserbehälter oder am Handgriff 1 vorgesehen sein, wobei die letztere Lösung eine einfachere Handhabung des erfindungsgemäßen Mundpflegegeräts ermöglicht.

Wie aus der Fig.1 zu erkennen ist, verläuft im rohrförmigen Mundstück 2 ein Wasserkanal 31, der einer lediglich schematisch gezeigten Düse 3 das von der Pumpe unter Druck gesetzte Wasser zuführt. Durch das von der Düse 3, gegebenenfalls pulsierend, abgegebene Wasser werden die damit beaufschlagten Zähne gereinigt sowie das Zahnfleisch
35 massiert. Die Arbeitsweise einer derartigen Munddusche

ist im übrigen bekannt, so daß nähere Erläuterungen entbehrllich erscheinen.

Erfindungsgemäß ist innerhalb des Handgriffs 1 eine
5 Low-Level-Laserbestrahlungsvorrichtung 10 angeordnet, die einen Laserstrahl erzeugt, der über einen Lichtleiter 11, der innerhalb des rohrförmigen Mundstücks 2 im wesentlichen parallel zum Wasserkanal 31 verläuft, zu einer Linse 12 geleitet wird, über die er schließlich austritt. Wie
10 insbesondere aus der Schnittansicht A-A zu erkennen ist, ist die Linse 12 etwas oberhalb der Düse 3 derart angeordnet, daß der Laserstrahl beim Gebrauch der Munddusche im wesentlichen auf das Zahnfleisch gerichtet ist. Gegebenenfalls ist es möglich, eine Linse mit einem großen
15 Streubereich zu verwenden, so daß entsprechend große Bereiche des Zahnfleisches vom Laserstrahl erfaßt werden. Weiterhin ist es möglich, den Laserstrahl über mehrere Linsen austreten zu lassen.

20 Die Low-Level-Laserbestrahlungsvorrichtung 10 wird über einen (nicht gezeigten) Schalter aktiviert.

Anstelle der im Ausführungsbeispiel gezeigten Munddusche kann es sich bei der erfindungsgemäßen Mundpflege-
25 vorrichtung auch um eine elektrische Zahnbürste handeln. Die Low-Level-Laserbestrahlungsvorrichtung 10 und insbesondere ihre Linse 12 werden hierbei in analoger Weise angeordnet. Die Low-Level-Laserbestrahlungsvorrichtung 10 kann aber auch ein separates bzw. eigenständiges Teil
30 beispielsweise in Form eines Laserstifts sein, der dem betreffenden Mundpflegesystem beigelegt wird.

Obgleich dies nicht gezeigt ist, kann für die Low-Level-Laserbestrahlungsvorrichtung 10 ein mechanischer
35 oder optoelektronischer Sensor vorgesehen werden, der erfaßt, ob sich das mundseitige Ende des Mundstücks 2 bzw.

die Linse 12 im Mund befindet oder nicht. Wenn dieser Sensor erkennt, daß dies nicht der Fall ist, das Mundstück 2 sich also außerhalb der Mundhöhle befindet, wird von einer (nicht gezeigten) Steuervorrichtung die Low-Level-Laserbestrahlungsvorrichtung abgeschaltet, so daß kein Laserstrahl erzeugt wird, der gegebenenfalls Schaden anrichten könnte.

Die erfindungsgemäße Low-Level-Laserbestrahlungsvorrichtung verwendet vorzugsweise einen Diodenlaser. Jedoch ist es möglich, andere geeignete Lasererzeugungsvorrichtungen zu verwenden. Die Wellenlänge des erzeugten Laserlichts liegt im Bereich zwischen 630 nm und 830 nm, also im Bereich des rötlichen Lichts. Wenn der Bereich der Wellenlänge bis auf 450 nm ausgedehnt wird, wird auch grünlisches Licht abgegeben.

Gegebenenfalls ist es auch möglich, die Low-Level-Laserbestrahlungsvorrichtung 10 nicht nur kontinuierlich, sondern auch pulsierend oder in anderer Weise mit wechselnder Ausgangsleistung zu betreiben, falls hierdurch die therapeutische Wirksamkeit gesteigert werden kann. Eine entsprechende Regelelektronik kann ohne weiteres im Handgriff 1 integriert werden.

25

In Fig.2 ist eine Ausführungsform des erfindungsgemäßen Geräts 200 zur Therapie und Prophylaxe von Rhinitis und Akne gezeigt.

Wie aus der Fig.2 hervorgeht, weist das erfindungsgemäße Gerät 200 ein Gehäuse 211 auf, das beispielsweise aus Metall oder einem geeigneten Kunststoffmaterial besteht. Das Gehäuse 211 ist nach Art eines Handgriffs etwa rund gefertigt, so daß das Gerät 200 in einer Hand gehalten und bedient werden kann.

35

Im Inneren des Gehäuses 211 ist eine wiederaufladbare Batterie 250 zur Stromversorgung vorgesehen, die über eine lediglich schematisch gezeigte Ladevorrichtung 260 am Stromnetz geladen werden kann. Alternativ kann es sich bei der Batterie auch um eine herkömmliche, nicht-wiederaufladbare Batterie handeln; weiterhin ist es möglich, das Gerät über eine Leitung (und ggf. einen zusätzlichen Trafo) direkt am Stromnetz zu betreiben.

Im Inneren des Gehäuses 211 ist eine Low-Level-Laserbestrahlungsvorrichtung vorgesehen, die aus einer Ansteuer-elektronik 214, die von der Batterie 250 gespeist wird, und einem Laserstrahl-Sendeelement in Form einer Laserdiode 216 besteht. Das von der Laserdiode 216 erzeugte Laserlicht wird in eine längliche, z.B. in die Nasenöffnung eines Patienten einführbare Lichtleitervorrichtung 220 eingespeist. Am Ende der Lichtleitervorrichtung 220 sitzt eine Streulinse 221 zur Fächerung des von der Laserdiode 216 abgegebenen Laserstrahls. Die Ausgangsleistung der Laserdiode 216 liegt zwischen 1 mW und 5 mW und entspricht damit der Klasse IIIA. Die Laserdiode 16 erzeugt einen Laserstrahl mit einer möglichen Wellenlänge im Bereich von 180 nm bis 1000 nm.

Zum Einschalten des Geräts ist ein Ein/Aus-Schalter 230 vorgesehen, während die Ausgangsleistung des Laserstrahl-Sendeelements 216 mittels eines Drehreglers 231 eingestellt werden kann.

Wie aus der Fig.2 ersichtlich ist, kann das Gerät 200 mit einer Hand so ergriffen werden, daß das Ende der Lichtleitervorrichtung 220 auf einfachste Weise in die Nase eingeführt werden kann. Das Naseninnere kann somit wirksam mit dem Laserlicht beaufschlagt werden. Somit kann eine gleichmäßige und ausreichende therapeutische

Behandlung der erkrankten Nasenschleimhäute mit wenigen Handgriffen erreicht werden.

Das vorstehend beschriebene Gerät 200 kann erfindungsgemäß auch zur Behandlung von Akne verwendet werden. Ferner ist es möglich, dieses Gerät zur Stimulation von Testosteron im Hoden einzusetzen. Aufgrund der hierdurch hervorgerufenen Erhöhung der Testosteron-Produktion wird eine Verbesserung der erektielen Potenz des betreffenden Patienten erreicht.

Um dem Patienten eine möglichst einfache bzw. komfortable Handhabung des erfindungsgemäßen Testosteron-Stimulationsgeräts zu ermöglichen, ist es ferner möglich, dieses als flexibles tragbares Netz oder als Kissen auszubilden, in dem die Low-Level-Laserbestrahlungsvorrichtung angeordnet ist und den Hoden über mehrere gleichmäßig verteilte Laserstrahl-Sendeelemente beaufschlagt. Ein solches Kissen kann um den Hoden herum angelegt und dann z.B. im Sitzen beispielsweise beim Lesen oder Fernsehen getragen werden.

Gemäß Fig.3A weist eine erste Ausführungsform des erfindungsgemäßen Innenohrstörungs-Behandlungsgeräts eine Low-Level-Laserbestrahlungsvorrichtung 310 auf, die in das Innere eines Brillengestells 320 in der Nähe des Bügels 321 desselben eingebaut ist. Die Laserbestrahlungsvorrichtung 310 wird über Kabel 310a aus einer (nicht gezeigten) Stromquelle in Form einer Batterie oder dergleichen gespeist. Der von der Laserbestrahlungsvorrichtung 310 abgegebene Laserstrahl wird über eine Lichtleitervorrichtung 311 einer Linse 312 zugeführt, aus der er austritt und auf den darunter liegenden Bereich einwirkt. Die Lichtleitervorrichtung 311 verläuft austrittsseitig in einem etwa rohrförmigen Ansatz 311a, der aus einem elastisch verformbaren Material besteht, so daß die Posi-

tion der Linse 312 und damit der Wirkungsbereich des erfindungsgemäßen Innenohrstörungs-Behandlungsgeräts geändert bzw. an den Patienten angepaßt werden kann. Da diese erste Ausführungsform in eine Brille integriert ist, wird
5 somit ein Kombinationsgerät geschaffen, das bei einem Brillenträger kaum weiter auffällt.

In Fig.3B ist eine weitere Ausführungsform des erfindungsgemäßen Innenohrstörungs-Behandlungsgeräts gezeigt,
10 das sich von der ersten Ausführungsform dadurch unterscheidet, daß es sich bei der Befestigungsvorrichtung 320 um einen Bügel handelt, der beispielsweise ein speziell für das Innenohrstörungs-Behandlungsgerät gefertigtes Teil darstellt. Der Bügel 320 kann aber auch Teil eines
15 Hörgeräts, eines Tinnitusmaskers oder eines Kombinationsgeräts aus einem Hörgerät und einem Tinnitusmasker sein. Im übrigen entspricht diese zweite Ausführungsform des Innenohrstörungs-Behandlungsgeräts der vorstehend beschriebenen ersten Ausführungsform, so daß bezüglich seiner
20 technischen Einzelheiten auf die vorstehende Beschreibung verwiesen werden darf.

Gemäß einer weiteren, in den Figuren nicht näher gezeigten Ausführungsform der Erfindung kann die Low-Level-
25 Laserbestrahlungsvorrichtung 310 eine separate Einheit sein, die beispielsweise in einer Tasche oder am Gürtel des Patienten getragen wird. In diesem Fall ist die Lichtleitervorrichtung 311 eine flexible Leitung, die in einer Linse endet, welche mittels der Befestigungsvorrichtung am Ohr befestigt werden kann. Diese Ausführungsform der Erfindung ist insbesondere dann von Vorteil,
30 wenn die Laserbestrahlungsvorrichtung 310 und/oder deren Batterie vergleichsweise schwer ist.

35 Für die Low-Level-Laserbestrahlungsvorrichtung 310 kann ein (in den Figuren nicht gezeigter) Ein/Aus-Schal-

ter vorgesehen werden, der es dem Patienten ermöglicht, die Behandlung zu beliebigen Zeiten vorzunehmen. Die Laserbestrahlungsvorrichtung 310 kann weiterhin eine manuelle Einstellvorrichtung aufweisen, mittels der ihre Ausgangsleistung und/oder die Wellenlänge des Laserstrahls auf einen geeigneten Wert eingestellt werden kann. Die Laserbestrahlungsvorrichtung 10 arbeitet entweder im kontinuierlichen oder im pulsierenden Betrieb, wobei gegebenenfalls eine Steuervorrichtung vorgesehen sein kann, mittels der die gewünschte Betriebsart und/oder die Impulsfrequenz eingestellt werden kann. Die Ausgangsleistung der Laserbestrahlungsvorrichtung 310 beträgt vorzugsweise zwischen 1 und 120 mW. Die Wellenlänge des Laserstrahls liegt im Bereich von 180 nm bis 1000 nm. Somit ist es möglich, handelsübliche Laserdioden als Strahlungsquelle zu verwenden.

Untersuchungen haben gezeigt, daß mit dem erfindungsgemäßen Gerät insbesondere dann gute Heilungserfolge erzielbar sind, wenn der Laserstrahl auf das Mastoid oder über den Gehörgang auf das Mittelohr einwirkt. Diese Bereiche des Ohres können durch geeignete Einstellung der Lichtleitervorrichtung 311 bestrahlt werden. Um eine noch bessere Heilungswirkung zu erzielen, kann das erfindungsgemäße Gerät gegebenenfalls dahingehend modifiziert werden, daß zwei Lichtleitervorrichtungen mit einer jeweiligen Linse vorgesehen werden, wobei die eine Linse auf das Mastoid und die andere Linse auf das Mittelohr einwirkt. Die Anzahl der Lichtleitervorrichtungen und Linsen kann selbstverständlich weiter erhöht werden, falls je nach der Art der Erkrankung des Innenohrs noch andere Bereiche des Ohres therapeutisch beaufschlagt werden sollen.

Gemäß Fig.4A besteht eine erste Ausführungsform des erfindungsgemäßen Geräts zur Stimulierung des Zentralnervensystems im wesentlichen aus einem Helm 41, der bei-

spielsweise wie ein Fahrradhelm aus geschäumtem Material oder aus einem anderen geeigneten Kunststoffmaterial besteht. Der Helm 41 weist eine Vielzahl geeigneter Bohrungen auf, in denen jeweils eine Low-Level-Laserbestrahlungsvorrichtung 410 eingesetzt ist. Bei dieser Low-Level-Laserbestrahlungsvorrichtung 410 kann es sich entweder um eine Laserdiode 411a handeln, die eine eigene Stromversorgung wie beispielsweise eine Batterie besitzt, oder aber um eine Laserdiode 11b, die über eine Stromversorgungsleitung 411d mit einer zentralen (nicht gezeigten) Stromversorgungseinrichtung verbunden ist.

Im Inneren des Helms 41 sind mehrere (nicht gezeigte) Abstandshalter vorgesehen, die dafür Sorge tragen, daß die nach innen gerichteten Austrittsöffnungen der Laserdioden 411a bzw. 411b einen vorbestimmten Abstand zur Kopfhaut des Patienten aufweisen. Hierdurch wird erreicht, daß der der jeweiligen Laserdiode 411a bzw. 411b zugeordnete Bereich der Kopfhaut des Patienten gleichmäßig und mit definierter Energie bestrahlt wird.

In Fig.4B ist eine weitere Ausführungsform des Helms gezeigt, die sich von der Ausführungsform der Fig.4A dadurch unterscheidet, daß als Laserstrahl-Sendeelemente Lichtleitervorrichtungen 411c vorgesehen sind, die beispielsweise von einer einzigen (nicht gezeigten) Lichtquelle gespeist werden. Alternativ hierzu kann für jedes oder zumindest für einen Teil der Lichtleitervorrichtungen 411c eine eigene Laserlichtquelle vorgesehen werden, so daß die Möglichkeit besteht, einige oder alle Lichtleitervorrichtungen 411c mit anderer Frequenz und/oder Leistung zu betreiben. Die Laserlichtquellen können entweder Teil des Helms 41 sein oder in einem externen Gerät angeordnet werden.

Die in Fig.4B gezeigte Variante des Helms hat somit den Vorteil, daß die Wellenlänge und/oder Energie der Laserstrahlen zentral gesteuert werden kann, wodurch die Ansteuerelektronik gegebenenfalls vereinfacht werden kann. Am im Inneren des Helms 41 liegenden Ende jeder Lichtleitervorrichtung 411c sitzt vorzugsweise eine (nicht gezeigte) Linse, die eine noch günstigere bzw. gleichmäßigere Verteilung des abgegebenen Laserlichts ermöglicht.

10

Wie aus der Fig.5 hervorgeht, besteht das erfindungsgemäße Gerät im wesentlichen aus einem Gehäuse 11, das erfindungsgemäße Gerät zur Therapie und Prophylaxe von Dekubitus beispielsweise aus Metall oder einem geeigneten Kunststoffmaterial besteht. Das Gehäuse 511 weist eine Vielzahl geeigneter Bohrungen auf, in denen jeweils eine Rohr 515 eingesetzt ist, das zusammen mit einem Gelenk 516 einen schwenkbaren Halter bildet. An diesem schwenkbaren Halter ist jeweils ein Laserstrahl-Sendeelement 517 befestigt, das beispielsweise aus einer Laserdiode besteht. Sämtliche Laserstrahl-Sendeelemente bzw. Dioden 517 bilden die Low-Level-Laserbestrahlungsvorrichtung 510. Die Laserstrahl-Sendeelemente 517 weisen ferner eine lediglich schematisch angedeutete Streulinse zur Fächerung des von ihnen abgegebenen Laserstrahls auf.

Das Gehäuse 511 ist mittels nicht näher gezeigter Einrichtungen an der Decke oder an einem geeigneten Ständer befestigt; das Gehäuse 511 beherbergt ferner sämtliche elektrischen und elektronischen Komponenten zur Ansteuerung der Laserstrahl-Sendeelemente 517. Zum Einschalten des Geräts ist ein (nicht gezeigter) Ein/Aus-Schalter vorgesehen, während die Ausgangsleistung der Laserstrahl-Sendeelemente 517 mittels eines Drehreglers eingestellt werden kann.

35

Wie aus der Fig.5 ersichtlich ist, werden die Laserstrahl-Sendeelemente 517 mittels der schwenkbaren Halter 515, 516 auf einen (nicht gezeigten) Patienten gerichtet, der sich auf einer Liege bzw. einem Bett 51 befindet.

5 Durch die Vielzahl der Laserstrahl-Sendeelemente 517 sowie aufgrund der mit den Streulinsen erzeugten Fächerung der Laserstrahlen kann eine gleichmäßige und ausreichende therapeutische Behandlung der erkrankten bzw. wundgelegenen Haut des Patienten mit wenigen Handgriffen erreicht

10 werden.

Anstelle separater Laserstrahl-Sendeelemente in Form von Laserdioden 517 können auch (nicht gezeigte) Lichtleitervorrichtungen vorgesehen werden, die beispielsweise

15 von einer einzigen (nicht gezeigten) Lichtquelle gespeist werden. Die Verwendung von Lichtleitern hat darüber hinaus den Vorteil, daß die Wellenlänge und/oder Energie der Laserstrahlen zentral gesteuert werden kann, wodurch die Ansteuerelektronik gegebenenfalls vereinfacht werden

20 kann. Die Laserstrahl-Sendeelemente 517 erzeugen einen Laserstrahl mit einer Wellenlänge im Bereich von 180 nm bis 1000 nm, wobei die Ausgangsleistung vorzugsweise zwischen 1 mW und 120 mW liegt.

25 Das Gehäuse 511 beinhaltet ferner eine (nicht gezeigte) manuell bedienbare Zeitschaltuhr, die nach Ablauf einer vorwählbaren Zeitspanne die Laserstrahl-Sendeelemente 517 deaktiviert. Der Therapeut kann somit nach geeigneter Einstellung bzw. Justierung des Geräts den Patienten

30 bis zum Ablauf der vorgewählten Zeitspanne alleine lassen. Als günstig haben sich in der Praxis Behandlungszeiträume von bis zu 30 Minuten erwiesen.

Die Laserstrahl-Sendeelemente 517 bzw. ihre Gelenke

35 516 können einen (nicht gezeigten) motorischen Antrieb aufweisen, der den Abstrahlwinkel der Laserstrahl-Sende-

elemente 517 ändert, so daß der abgegebene Laserstrahl einen entsprechenden Bereich der Hautoberfläche gleichsam abtastet. Hierdurch ist es möglich, diesen Bereich der Haut des Patienten in zyklischer Folge mit den Laserstrahlen zu beaufschlagen. Somit kann die therapeutische Wirkung ggf. gleichmäßig gemacht werden. Ferner ist es hierdurch möglich, Laserstrahl-Sendeelemente 517 mit größerer Leistung einzusetzen, da die jeweiligen Hautbereiche aufgrund der motorischen Verstellung nur kurzzeitig beaufschlagt werden.

Gemäß Fig.6A besteht eine Ausführungsform eines Geräts zur Biostimulation von Pflanzen im wesentlichen aus einem Ständer 612, der beispielsweise aus einem Rohr aus Metall oder einem geeigneten Kunststoffmaterial besteht. Der Ständer 612 weist eine Vielzahl geeigneter Bohrungen auf, in denen jeweils eine waagrecht verlaufende Stange 615 eingesetzt ist, die zusammen mit einem Gelenk 616 einen schwenkbaren Halter bildet. An diesem schwenkbaren Halter ist jeweils ein Laserstrahl-Sendeelement 617 befestigt, das beispielsweise aus einer Laserdiode besteht. Sämtliche Laserstrahl-Sendeelemente bzw. Dioden 617 bilden die erfindungsgemäße Low-Level-Laserbestrahlungsvorrichtung 10. Die Laserstrahl-Sendeelemente 617 weisen ferner eine lediglich schematisch angedeutete Streulinse zur Fächerung des von ihnen abgegebenen Laserstrahls auf.

Der Ständer 612 ist in einem Gehäuse 611 befestigt, das gleichzeitig als Standfuß dient und sämtliche elektrischen und elektronischen Komponenten zur Ansteuerung der Laserstrahl-Sendeelemente 617 beherbergt. Zum Einschalten des Geräts ist ein Ein/Aus-Schalter 613 vorgesehen, während die Ausgangsleistung der Laserstrahl-Sendeelemente 617 mittels eines Drehreglers 614 eingestellt werden kann.

Wie aus der Fig.6A ersichtlich ist, werden die Laserstrahl-Sendeelemente 617 mittels der schwenkbaren Halter 615, 616 auf eine Pflanze 62 gerichtet, die sich in einem Topf 61 befindet. Durch die Vielzahl der Laserstrahl-Sendeelemente 617 sowie aufgrund der mit den Streulinsen erzeugten Fächerung der Laserstrahlen kann eine gleichmäßige und ausreichende Biostimulierung der Pflanze 2 mit wenigen Handgriffen erreicht werden.

10

In Fig.6B ist eine weitere Ausführungsform des erfindungsgemäßen Geräts gezeigt, das sich von der Ausführungsform der Fig.6A dadurch unterscheidet, daß die Laserstrahl-Sendeelemente 617 samt ihren schwankbaren Haltern 615, 616 an einem Gehäuse 611' befestigt sind, das zur Deckenmontage vorgesehen ist. Im übrigen arbeitet dieses Gerät in gleicher Weise wie das Gerät der Fig.6A.

Anstelle separater Laserstrahl-Sendeelemente in Form von Laserdioden 617 können auch (nicht gezeigte) Lichtleitervorrichtungen vorgesehen werden, die beispielsweise von einer einzigen (nicht gezeigten) Lichtquelle gespeist werden. Diese Ausführungsform bietet sich ggf. für größere Räume wie Gewächshäuser und dergleichen an. Die Verwendung von Lichtleitern hat darüber hinaus den Vorteil, daß die Wellenlänge und/oder Energie der Laserstrahlen zentral gesteuert werden kann, wodurch die Ansteuerelektronik gegebenenfalls vereinfacht werden kann.

Die Laserstrahl-Sendeelemente 617 erzeugen einen Laserstrahl mit einer Wellenlänge im Bereich von 180 nm bis 1000 nm, wobei die Ausgangsleistung vorzugsweise zwischen 1 mW und 500 mW liegt.

Das Gehäuse 611 bzw. 611' beinhaltet ferner eine (nicht gezeigte) manuell bedienbare oder automatisch ar-

beitende Steuereinrichtung, die in Abhängigkeit von der Wachstumsphase der Pflanze 61 eines oder mehrere der Laserstrahl-Sendeelemente 617 mit jeweils geeigneter Wellenlänge aktiviert und/oder deren Ausgangsleistung ändert. Somit ist eine optimale Anpassung an das Wachstum der Pflanze 61 möglich. Die Einstellung der Wellenlänge bzw. der Ausgangsleistung kann ggf. auch über eine Zeitsteuerung erfolgen, wenn das Wachstumsverhalten der Pflanze 61 bekannt ist.

Ansprüche

1. Mundpflegegerät, mit einem Handgriff (1) und einem in den Mund einführbaren Mundstück (2), an dem eine Mundpflegevorrichtung (3) sitzt,
5 *gekennzeichnet durch*
eine Low-Level-Laserbestrahlungsvorrichtung (10), deren Laserstrahl über das Mundstück (2) in den Mund projizierbar ist.
- 10
2. Mundpflegegerät nach Anspruch 1, *dadurch gekennzeichnet, daß* die Low-Level-Laserbestrahlungsvorrichtung (10) im Handgriff (1) untergebracht ist, wobei der von ihr erzeugte Laserstrahl über eine Lichtleitervorrichtung (11)
15 durch das Mundstück (2) verläuft und an dessen mundseitigem Ende vorzugsweise über eine Linse (12) austritt.
3. Mundpflegegerät nach Anspruch 2, *dadurch gekennzeichnet, daß* der Austritt der Lichtleitervorrichtung (11) bzw.
20 die Linse (12) am mundseitigen Ende des Mundstücks (2) so angeordnet ist, daß der Laserstrahl beim Gebrauch des Geräts im wesentlichen auf das Zahnfleisch gerichtet ist.
4. Mundpflegegerät nach einem der Ansprüche 1 bis 3, *dadurch gekennzeichnet, daß* ein Sensor vorgesehen ist, der erfaßt, ob sich das mundseitige Ende des Mundstücks (2) bzw. die Linse (12) im Mund befindet oder nicht, und der die Low-Level-Laserbestrahlungsvorrichtung (10) abschaltet, wenn dies nicht der Fall ist.
30
5. Mundpflegegerät nach einem der Ansprüche 1 bis 4, *dadurch gekennzeichnet, daß* die Mundpflegevorrichtung (3) elektrisch betrieben ist.
- 35
6. Mundpflegegerät nach Anspruch 5, *dadurch gekennzeichnet, daß* die Low-Level-Laserbestrahlungsvorrichtung (10)

mit einem für die elektrisch betriebene Mundpflegevorrichtung (3) vorgesehenen Schalter ein- und ausschaltbar ist.

5 7. Mundpflegegerät nach Anspruch 5 oder 6, *dadurch gekennzeichnet*, daß die elektrisch betriebene Mundpflegevorrichtung (3) eine Munddusche ist.

10 8. Mundpflegegerät nach Anspruch 5 oder 6, *dadurch gekennzeichnet*, daß die elektrisch betriebene Mundpflegevorrichtung (3) eine Zahnbürste ist.

15 9. Mundpflegegerät nach einem der Ansprüche 5 bis 8, *dadurch gekennzeichnet*, daß die Mundpflegevorrichtung (3) von einer im Handgriff (1) vorgesehenen, vorzugsweise aufladbaren Batterie gespeist wird.

20 10. Gerät (200) zur Therapie von Rhinitis und Akne, *gekennzeichnet durch*
eine in einem Einhandgehäuse (211) befindliche Low-Level-Laserbestrahlungsvorrichtung (214, 216), die mindestens einen Laserstrahl erzeugt, der über eine im wesentlichen längliche, in die Nasenöffnung eines Patienten einführbare Lichtleitervorrichtung (220) auf das Naseninnere ein-
25 wirkt bzw. auf die von Akne befallenen Bereiche der Haut eines Patienten projizierbar ist.

30 11. Gerät nach Anspruch 10, *dadurch gekennzeichnet*, daß die Lichtleitervorrichtung (220) zumindest bereichsweise flexibel ausgebildet ist.

35 12. Gerät nach Anspruch 10 oder 11, *dadurch gekennzeichnet*, daß am austrittseitigen Ende der Lichtleitervorrichtung (220) eine Streulinse (221) zur Fächerung des Laserstrahls sitzt.

13. Gerät nach einem der Ansprüche 10 bis 12, *dadurch gekennzeichnet*, daß zur Stromversorgung der Low-Level-Laserbestrahlungsvorrichtung (214,216) eine im Einhandgehäuse (211) befindliche, vorzugsweise aufladbare Batterie (250) vorgesehen ist.

14. Gerät (200) zur Stimulation von Testosteron im Hoden, *gekennzeichnet durch* eine Low-Level-Laserbestrahlungsvorrichtung (214, 216), die mindestens einen Laserstrahl erzeugt, der auf den Hoden einwirkt.

15. Gerät nach Anspruch 14, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung (214,216) in einem Einhandgehäuse (211) angeordnet ist und den Laserstrahl über eine zumindest bereichsweise flexibel ausgebildete Lichtleitervorrichtung (220) abgibt.

16. Gerät nach Anspruch 15, *dadurch gekennzeichnet*, daß am austrittseitigen Ende der Lichtleitervorrichtung (220) eine Streulinse (221) zur Fächerung des Laserstrahls sitzt.

17. Gerät nach Anspruch 14, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung (214,216) in einem flexiblen tragbaren Netz angeordnet ist und den Hoden über mehrere gleichmäßig verteilte Laserstrahl-Sendeelemente beaufschlagt.

18. Gerät nach einem der Ansprüche 14 bis 17, *dadurch gekennzeichnet*, daß zur Stromversorgung der Low-Level-Laserbestrahlungsvorrichtung (214,216) eine im Einhandgehäuse (211) befindliche bzw. am Netz angeschlossene, vorzugsweise aufladbare Batterie (250) vorgesehen ist.

19. Innenohrstörungs-Behandlungsgerät zur Therapie einer chronischen komplexen Innenohrstörung eines Patienten, insbesondere zur Behandlung von Tinnitus und Vertigo,
gekennzeichnet durch

5 eine Low-Level-Laserbestrahlungsvorrichtung (310), die mittels einer Befestigungsvorrichtung (320) lösbar derart am Ohr eines Patienten befestigbar ist, daß der Laserstrahl auf mindestens einen vorbestimmten Bereich des Ohres einwirkt.

10

20. Innenohrstörungs-Behandlungsgerät nach Anspruch 19, *dadurch gekennzeichnet, daß* die Low-Level-Laserbestrahlungsvorrichtung (310) auf das Mastoid und/oder über den Gehörgang auf das Mittelohr einwirkt.

15

21. Innenohrstörungs-Behandlungsgerät nach Anspruch 19 oder 20, *dadurch gekennzeichnet, daß* die Low-Level-Laserbestrahlungsvorrichtung (310) in der Befestigungsvorrichtung (320) untergebracht ist und auf den/die vorbestimmten
20 Bereich(e) des Ohres über eine jeweilige Lichtleitervorrichtung (311) und eine an deren Ende sitzende Linse (312) einwirkt.

22. Innenohrstörungs-Behandlungsgerät nach einem der Ansprüche 19 bis 21, *dadurch gekennzeichnet, daß* die Low-Level-Laserbestrahlungsvorrichtung (310) eine separate
25 Einheit ist, deren Laserstrahl über eine flexible Lichtleitervorrichtung (311) einer an ihrem Ende sitzenden Linse (312) zugeführt wird, wobei die Linse (312) und/oder
30 das Ende der Lichtleitervorrichtung (311) mittels der Befestigungsvorrichtung (320) am Ohr befestigbar ist.

23. Innenohrstörungs-Behandlungsgerät nach einem der Ansprüche 19 bis 21, *dadurch gekennzeichnet, daß* die Befestigungsvorrichtung (320) ein Brillengestell, ein Hörge-
35

rät, ein Tinnitusmasker oder ein Kombinationsgerät aus einem Tinnitusmasker und einem Hörgerät ist.

24. Innenohrstörungs-Behandlungsgerät nach einem der Ansprüche 19 bis 23, *dadurch gekennzeichnet*, daß die Befestigungsvorrichtung (320) ein am Ohr befestigbarer Bügel, ein in das Ohr einführbares Teil oder ein auf den Kopf aufstülpbarer Bügel ist.

10 25. Gerät zur Stimulierung des Zentralnervensystems eines Patienten,

gekennzeichnet durch

eine Low-Level-Laserbestrahlungsvorrichtung (410), die mindestens einen Laserstrahl erzeugt, der auf mindestens einen vorbestimmten Bereich der Haut des Patienten, vorzugsweise in unmittelbarer Nähe des zu stimulierenden Zentralnervensystems, einwirkt.

26. Gerät nach Anspruch 25, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung (410) auf den Kopf des Patienten einwirkt.

27. Gerät nach Anspruch 26, *gekennzeichnet durch* einen helm- oder haubenartigen Aufsatz (41) für den Kopf des Patienten, wobei der Aufsatz eine Vielzahl von Laserstrahl-Sendeelementen (411a; 411b; 411c) trägt, deren Laserstrahlen ins Innere des Aufsatzes (41) gerichtet sind.

28. Gerät nach Anspruch 27, *dadurch gekennzeichnet*, daß der Aufsatz (41) an einem schwenkbaren Halter befestigt ist.

29. Gerät nach Anspruch 27, *dadurch gekennzeichnet*, daß im Inneren des Aufsatzes (41) Abstandshalter vorgesehen sind, die die Innenwand des Aufsatzes (41) und damit die

Laserstrahl-Sendeelemente (411a; 411b; 411c) in einem vorbestimmten Abstand zur Kopfhaut des Patienten halten.

30. Gerät nach Anspruch 29, *dadurch gekennzeichnet*, daß
5 die Laserstrahl-Sendeelemente (411a; 411b; 411c) jeweils von einer eigenen Batterie oder aus einer zentralen Stromversorgungseinrichtung gespeist sind.

31. Gerät nach einem der Ansprüche 27 bis 30, *dadurch gekennzeichnet*, daß jedes Laserstrahl-Sendeelement aus einer
10 Lichtleitervorrichtung (411c) und ggf. einer an deren Ende sitzenden Linse gebildet ist.

32. Gerät nach einem der Ansprüche 25 bis 31, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung
15 (410) Teil eines Ganzkörperbehandlungsgeräts nach Art einer Sonnenbank ist bzw. in eine solche integriert ist.

33. Gerät zur Therapie und Prophylaxe von Dekubitus,
20 *gekennzeichnet durch*
eine Low-Level-Laserbestrahlungsvorrichtung (510), die mindestens einen Laserstrahl erzeugt, der auf bestimmte Bereiche der Haut eines Patienten einwirkt.

34. Gerät nach Anspruch 33, *dadurch gekennzeichnet*, daß
25 die Low-Level-Laserbestrahlungsvorrichtung (510) eine Vielzahl von Laserstrahl-Sendeelementen (517) aufweist.

35. Gerät nach Anspruch 34, *dadurch gekennzeichnet*, daß
30 mindestens einige der Laserstrahl-Sendeelemente (517) Laserstrahlen mit jeweils unterschiedlicher Wellenlänge erzeugen.

36. Gerät nach Anspruch 34 oder 35, *dadurch gekennzeichnet*, daß die Laserstrahl-Sendeelemente (517) jeweils an
35 einem schwenkbaren Halter (515, 516) befestigt sind.

37. Gerät nach Anspruch 34 oder 35, *dadurch gekennzeichnet*, daß das Licht jedes Laserstrahl-Sendeelements (517) über eine Lichtleitervorrichtung auf den Patienten ein-
5 wirkt.

38. Gerät nach einem der Ansprüche 35 bis 37, *dadurch gekennzeichnet*, daß eine Zeitschaltuhr vorgesehen ist, die nach Ablauf einer vorwählbaren Zeitspanne die Laser-
10 strahl-Sendeelemente (517) deaktiviert.

39. Gerät nach einem der Ansprüche 35 bis 38, *dadurch gekennzeichnet*, daß die Laserstrahl-Sendeelemente (517) eine Streulinse zur Fächerung des Laserstrahls aufweisen.
15

40. Gerät nach einem der Ansprüche 35 bis 39, *dadurch gekennzeichnet*, daß der Abstrahlwinkel der Laserstrahl-Sendeelemente (517) motorisch veränderbar ist.

20 41. Gerät nach Anspruch 40, *dadurch gekennzeichnet*, daß der Abstrahlwinkel der Laserstrahl-Sendeelemente (517) motorisch in der Weise zyklisch veränderbar ist, daß ein bestimmter Bereich der Haut des Patienten in zyklischer Folge mit den Laserstrahlen beaufschlagt wird.

25 42. Gerät zur Biostimulation von Pflanzen,
gekennzeichnet durch
eine Low-Level-Laserbestrahlungsvorrichtung (610), die mindestens einen Laserstrahl erzeugt, der auf bestimmte
30 Bereiche der Oberfläche der Pflanzen (62) einwirkt.

43. Gerät nach Anspruch 42, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung (610) eine Vielzahl von Laserstrahl-Sendeelementen (617) aufweist.
35

44. Gerät nach Anspruch 43, *dadurch gekennzeichnet*, daß mindestens einige der Laserstrahl-Sendeelemente (617) Laserstrahlen mit jeweils unterschiedlicher Wellenlänge erzeugen.
- 5
45. Gerät nach Anspruch 43 oder 44, *dadurch gekennzeichnet*, daß die Laserstrahl-Sendeelemente (617) jeweils an einem schwenkbaren Halter (615, 616) befestigt sind.
- 10 46. Gerät nach Anspruch 43 oder 44, *dadurch gekennzeichnet*, daß das Licht jedes Laserstrahl-Sendeelements (617) über eine Lichtleitervorrichtung auf die Pflanzen (62) einwirkt.
- 15 47. Gerät nach einem der Ansprüche 44 bis 46, *dadurch gekennzeichnet*, daß eine manuell bedienbare oder automatisch arbeitende Steuereinrichtung vorgesehen ist, die in Abhängigkeit von der Wachstumsphase der Pflanzen (62) eines oder mehrere Laserstrahl-Sendeelemente (617) mit je-
- 20 weils geeigneter Wellenlänge aktiviert und/oder deren Ausgangsleistung ändert.
48. Gerät nach einem der Ansprüche 44 bis 47, *dadurch gekennzeichnet*, daß die Laserstrahl-Sendeelemente (617) eine
- 25 Streulinse zur Fächerung des Laserstrahls aufweisen.
49. Gerät nach einem der Ansprüche 1 bis 48, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung einen Laserstrahl mit einer Wellenlänge im Bereich
- 30 von 180 nm bis 1000 nm, vorzugsweise im Bereich von 300 nm bis 700 nm erzeugt.
50. Gerät nach einem der Ansprüche 1 bis 49, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrich-
- 35 tung einen Laserstrahl mit einer Ausgangsleistung zwi-

schen 1 mW und 500 mW, vorzugsweise zwischen 1 mW und 5 mW (Klasse IIIA) abgibt.

- 5 **51.** Gerät nach einem der Ansprüche 1 bis 50, *dadurch gekennzeichnet*, daß die Ausgangsleistung der Low-Level-Laserbestrahlungsvorrichtung und/oder daß die Wellenlänge des Laserstrahls mittels einer Hand-Einstellvorrichtung auf einen wählbaren Wert einstellbar ist.
- 10 **52.** Gerät nach einem der Ansprüche 1 bis 51, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung den Laserstrahl im kontinuierlichen oder pulsierenden Betrieb abgibt.
- 15 **53.** Gerät nach einem der Ansprüche 1 bis 52, *dadurch gekennzeichnet*, daß die Low-Level-Laserbestrahlungsvorrichtung mindestens ein Laserstrahl-Sendeelement in Form einer Laserdiode aufweist.

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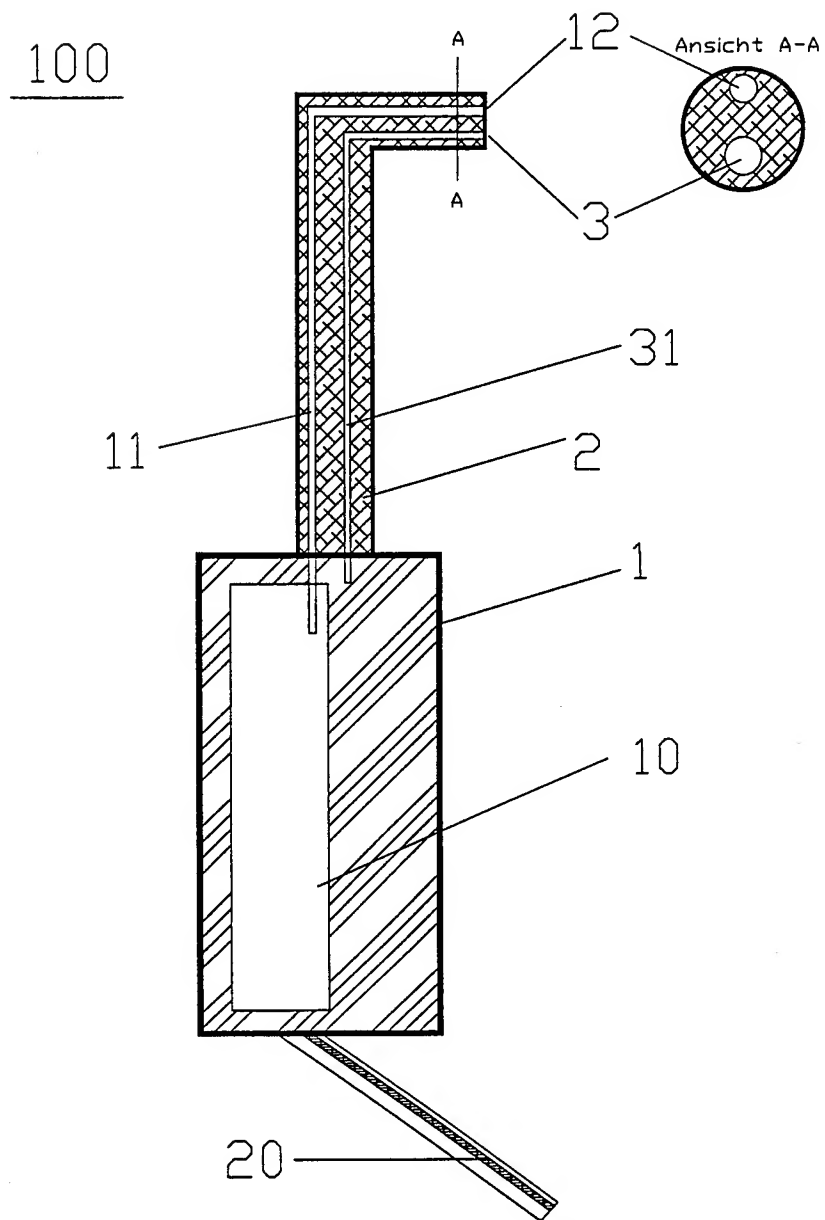
Fig. 1

Fig. 2

200

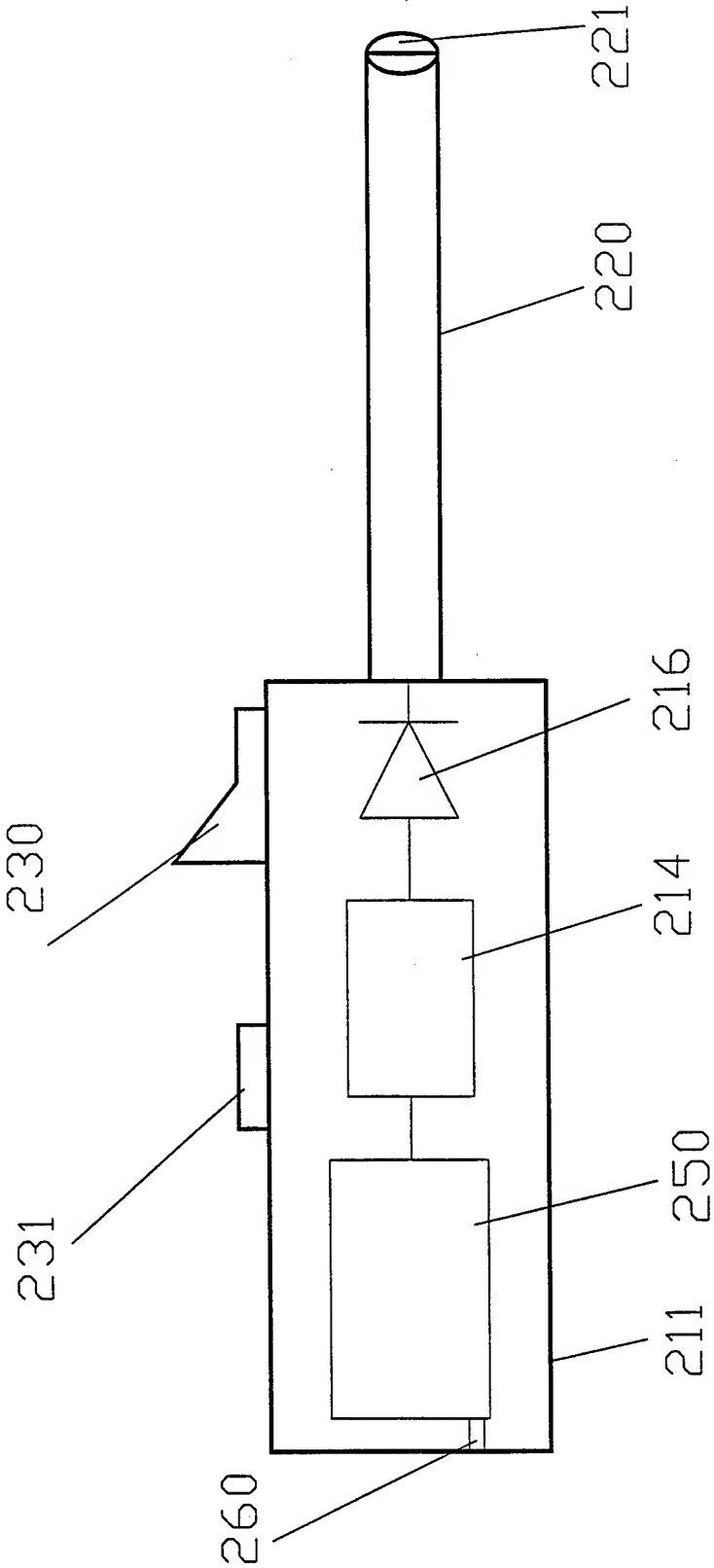
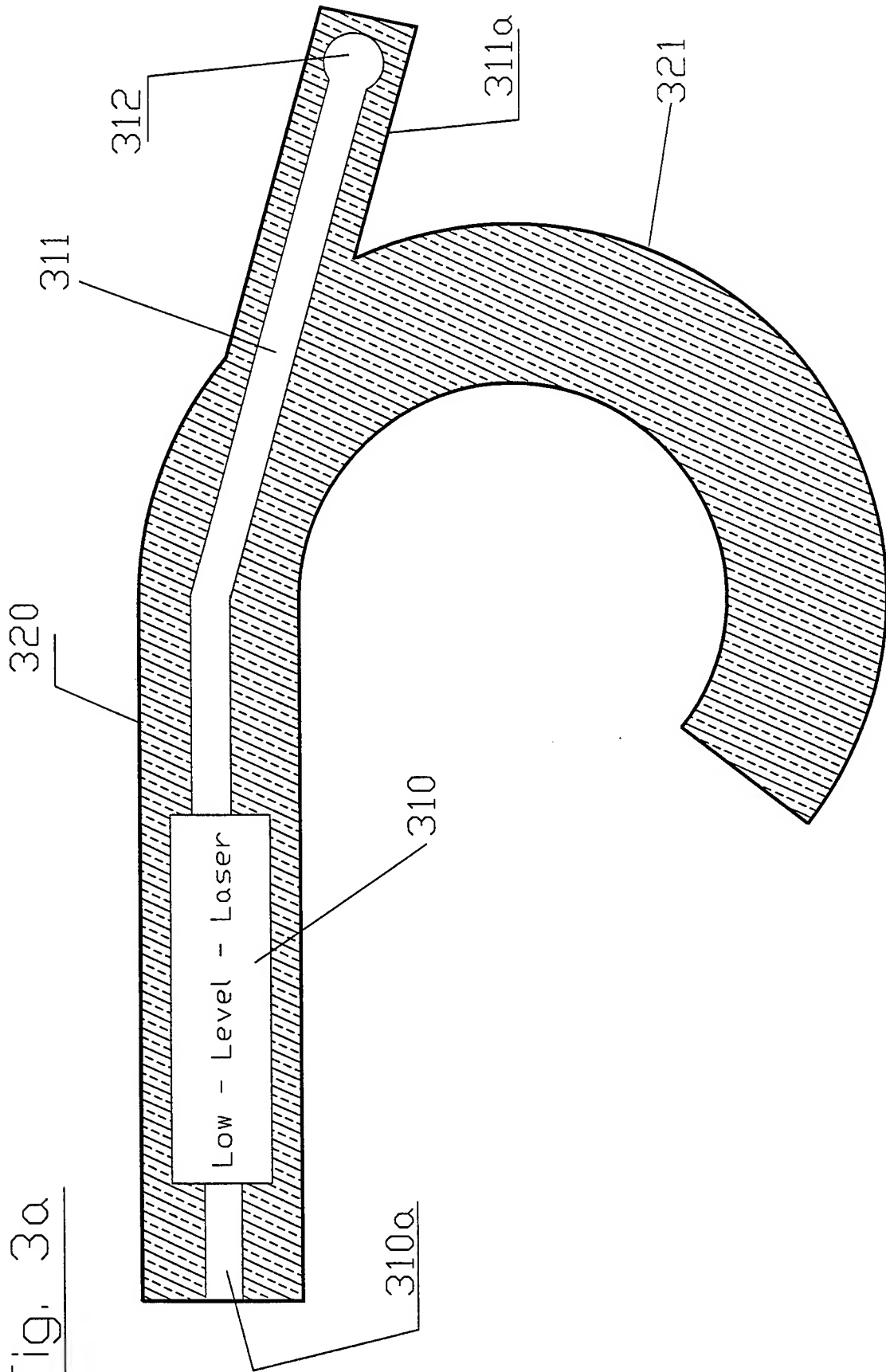
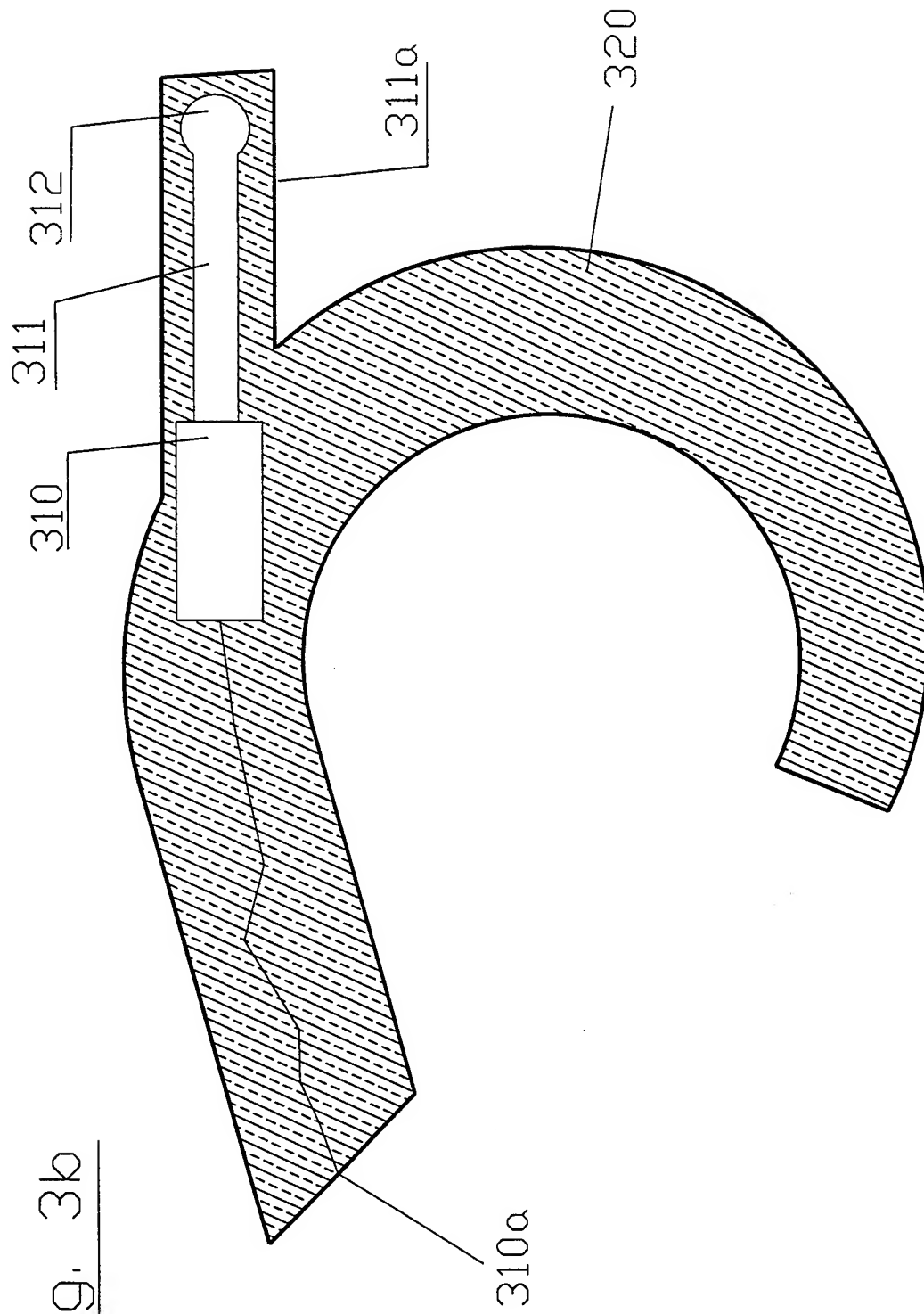


Fig. 3a





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Fig. 4a

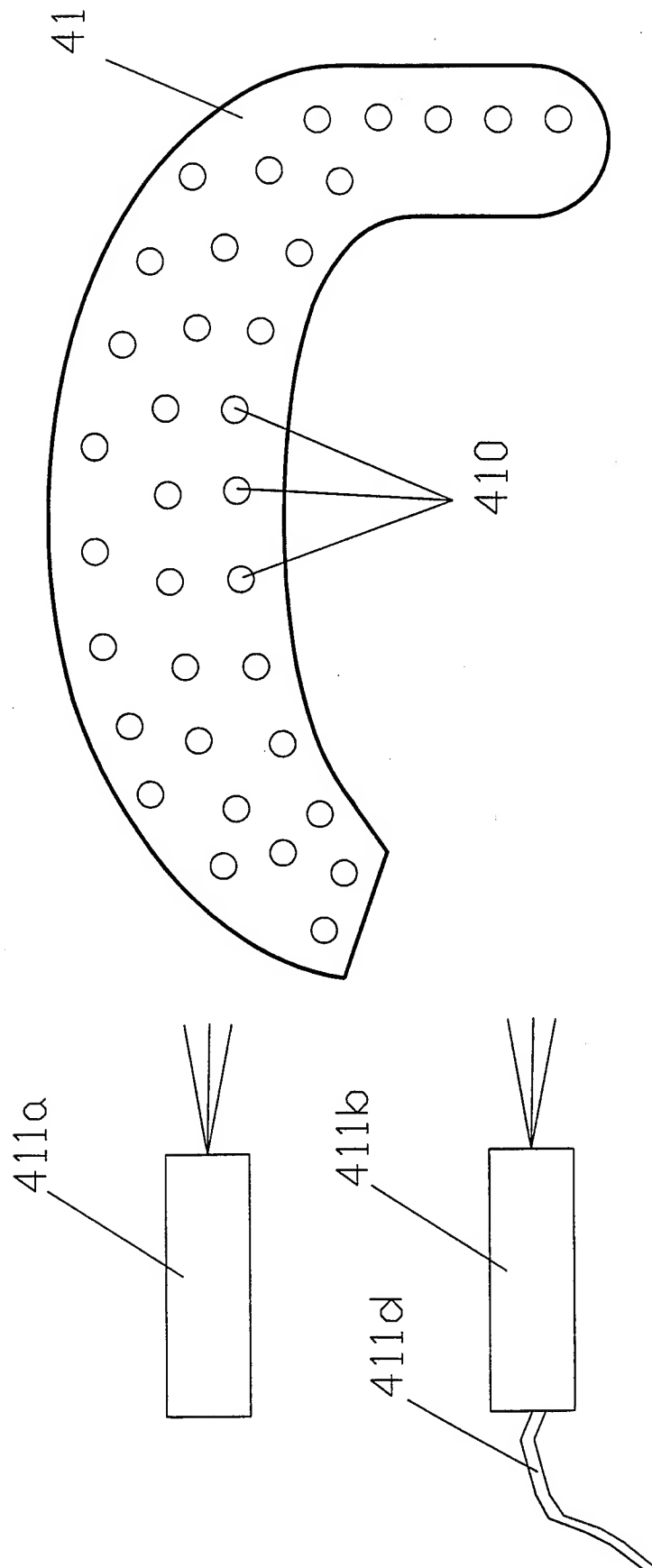


Fig. 4b

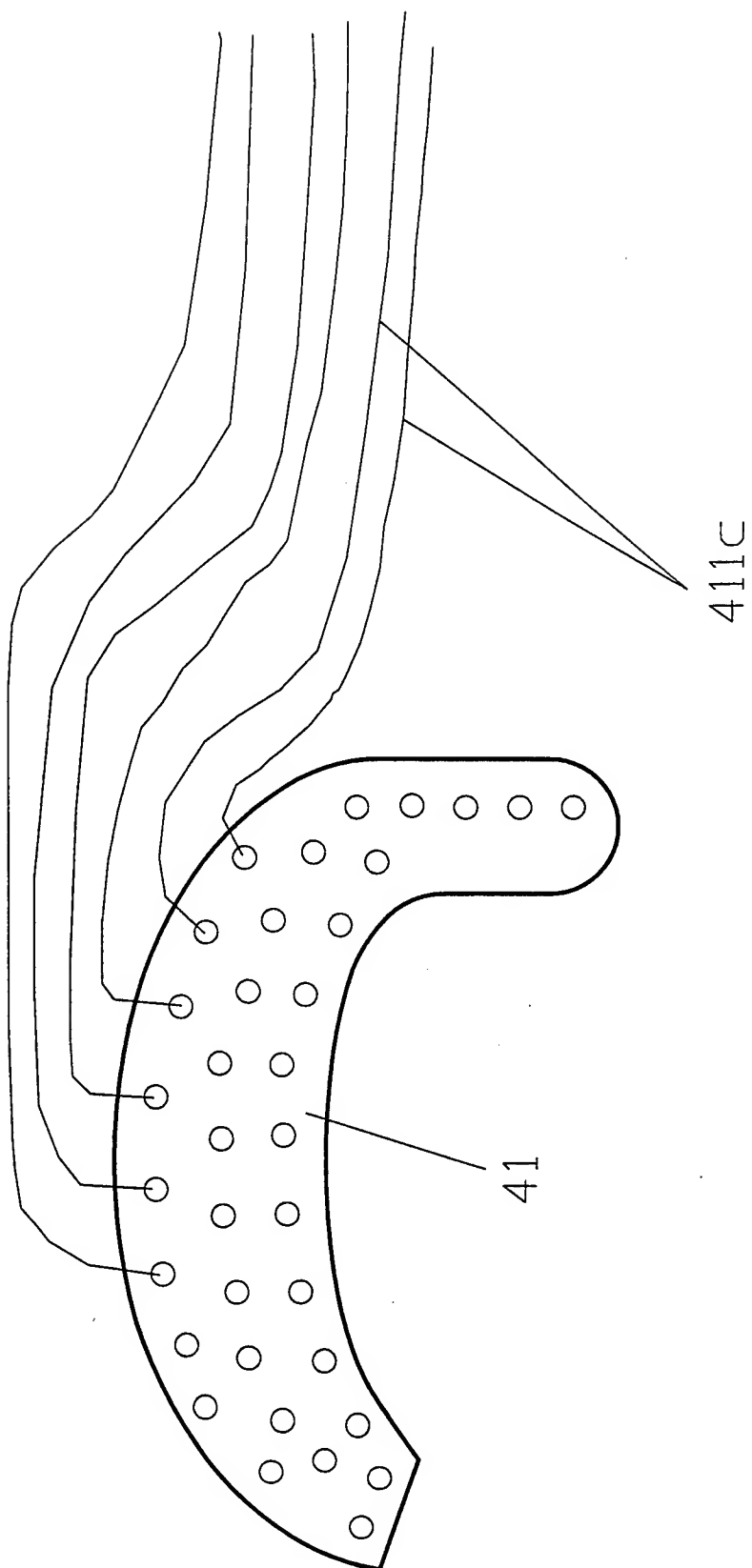


Fig. 5

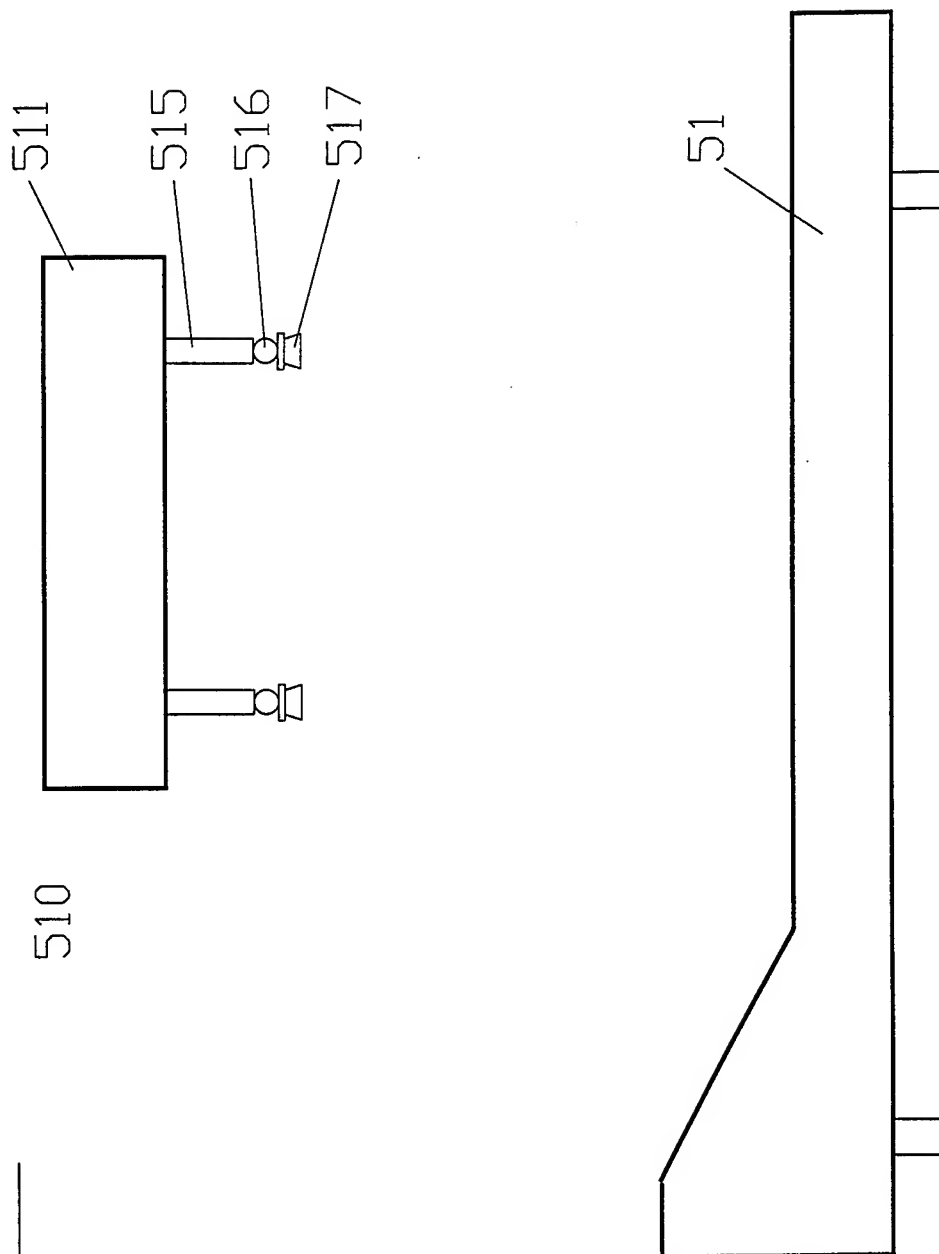


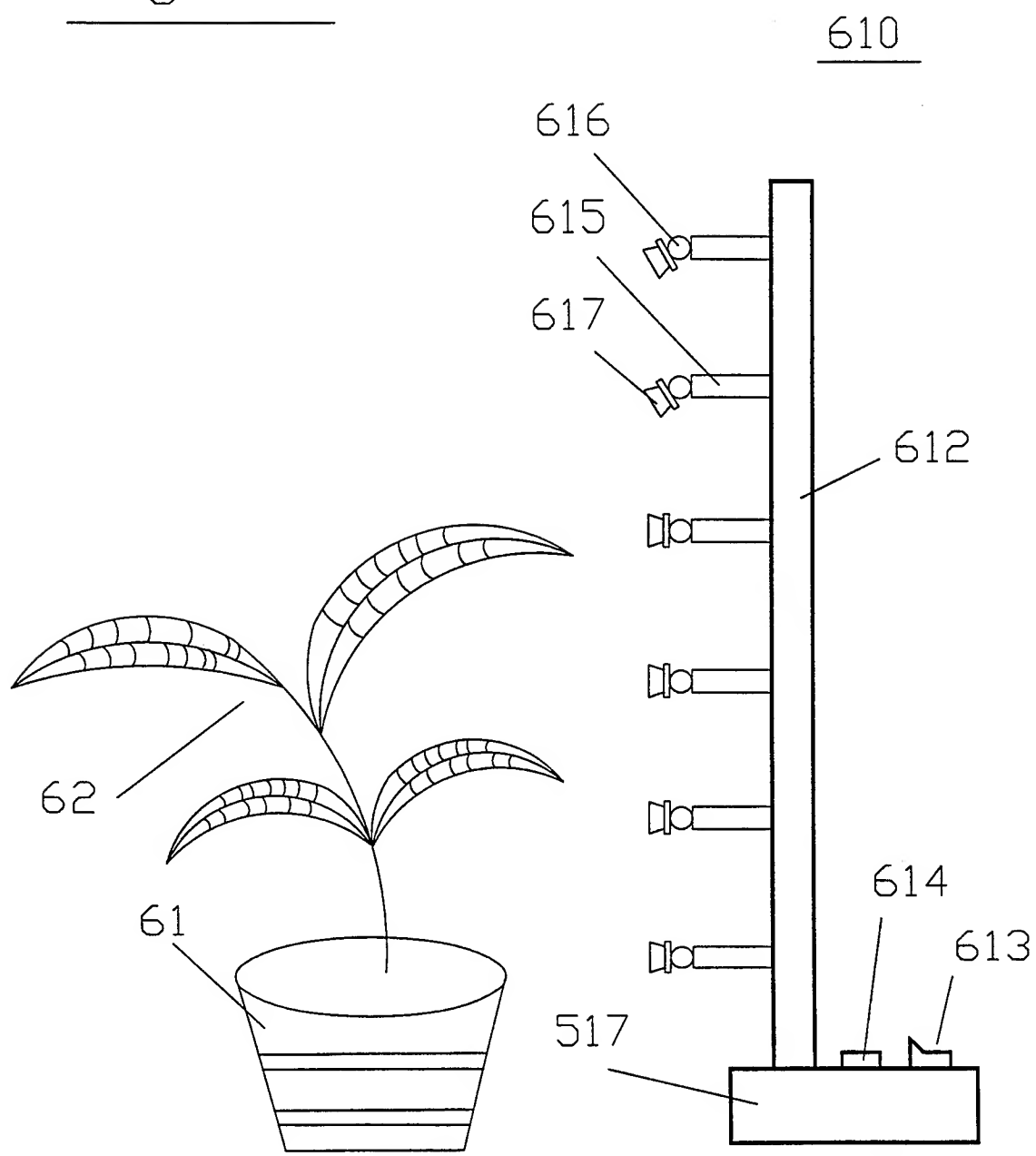
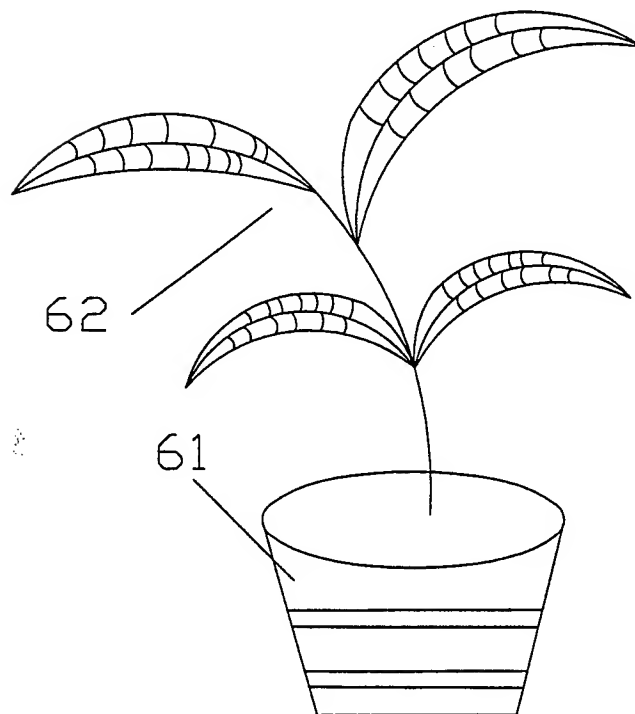
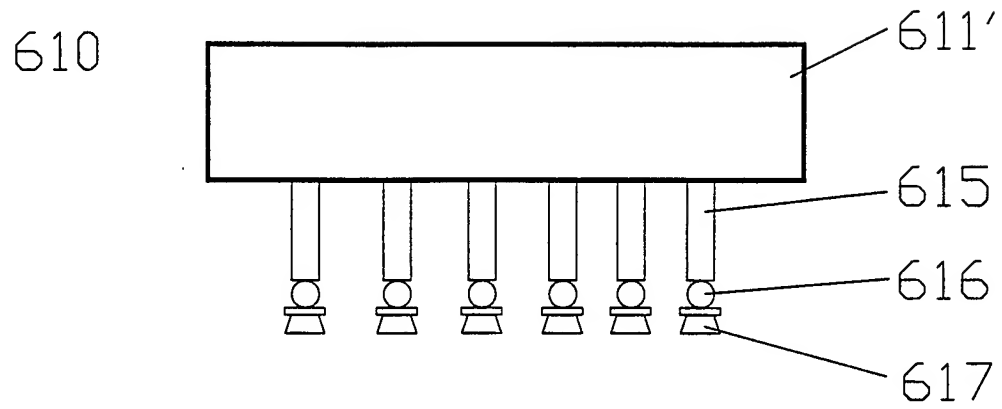
Fig. 6a

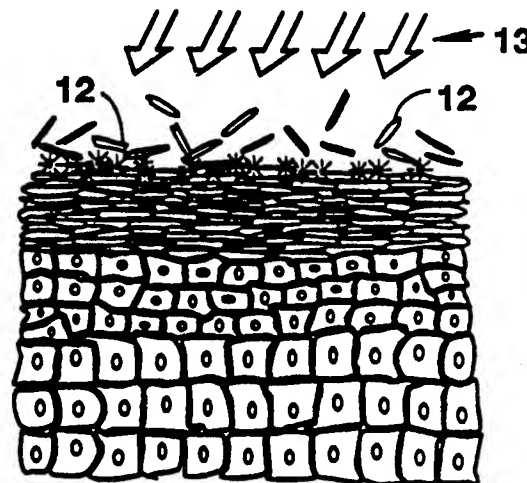
Fig. 6b

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(54) Title: SKIN TREATMENT PROCESS USING LASER**(57) Abstract**

This invention is a skin treatment process for the removal of superficial epidermal skin cells (12); the reduction or removal of unwanted hair (28); and the mitigation of skin conditions such as acne and seborrhea. A contaminant (4) having a high absorption at a wavelength of light is topically applied to a skin section. A preferred contaminant is a mixture of 20 % of one micron graphite particles in mineral oil. Portions of the contaminant are forced into spaces between the superficial epidermal skin cells, into hair ducts in the skin, and/or into adjacent sebaceous glands. The skin section is illuminated with laser pulses at the matching wavelength, so as to impart sufficient energy to the contaminant to cause explosion of the particles in the contaminant. The energy released by the explosions blows off layers of dead skin cells, and/or destroys tissue responsible for hair growth, and/or sebum production.



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SKIN TREATMENT PROCESS USING LASER

This invention is a continuation in part of Serial No. 08/280928 filed 7/26/94, Serial No. 08/257,021 scheduled to issue as Patent No. 5,423,803 on 6/13/95, and Serial No. 08/005,810 filed 1/19/93, scheduled to issue Patent
5 No. 5,425,728 on 6/20/95 which was a continuation in part of Serial No. 07/783,789 filed 10/29/91, now Patent No. 5,226,907 issued July 13, 1993. This invention relates to processes for skin treatment and in particular to such processes which will utilize lasers.

BACKGROUND OF THE INVENTION

10

The Skin

A section of human skin showing a cross section of one hair is shown in FIG. 1. FIG. 1 shows the hair shaft 33 of a hair growing in a hair duct 31, from dermal papilla 32, a nerve ending 34, a sweat gland 35 a sebaceous gland 38, arteries 36 and veins 37.

15

Three major concerns relating to human skin are (1) accumulation of excess layers of dead skin cells on middle age and elderly people which cause them to appear older, (2) skin conditions such as acne and seborrhea and (3) unwanted hair.

Dead Layers of Skin

20

The epidermis, 39 in FIG. 1, of the human skin comprises several distinct layers of skin tissue. These layers of tissue are depicted in block diagram form in FIG. 2. The deepest layer is the stratum basale layer which consists of columnar cells. The next layer up is the stratum spinosum composed of polyhedral cells. Cells pushed up from the stratum spinosum are
25 flattened and synthesize keratohyalin granules to form the stratum granulosum layer. As these cells move outward they lose their nuclei and the keratohyalin granules fuse and mingle with tonofibrils. This forms a clear layer called the stratum lucidum. The cells of the stratum lucidum are closely packed. As the cells move up from the stratum lucidum they become compressed into many

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layers of opaque squamas. These flattened cells have become completely filled with keratin and have lost all other internal structure, including nuclei. These squamas constitute the outer layer of the epidermis, the stratum corneum. At the bottom of the stratum corneum the cells are closely compacted and adhere
5 to one another strongly, but higher in the stratum they become loosely packed and eventually flake away at the surface. For example, in the cheek skin of a 50 year old face the outer layer of the stratum corneum typically consists of about 15 layers, and the layers flake away at the rate of about one or two layers per month. So we naturally get a completely new stratum corneum on
10 our faces about twice per year.

It is well known that the removal of a few surface layers of a person's skin will generally result in younger looking skin. Many techniques have been tried to produce this effect. A mild sunburn will cause slight blistering of the skin after which an outside layer of the skin peels off. This
15 generally leaves a younger looking skin surface. Similar results can be obtained by abrasion processes such as actually scraping away the surface layer with an abrasive material such as fine sand paper.

Recent attempts have been made to utilize laser beams to "cook" the surface layer of skin. This cooking causes the skin to blister after which the
20 surface layers can be scraped away. Also, people have been experimenting with lasers which vaporize the outside surface. These prior art processes present some beneficial results but also provide potential risk to the patient. The slight sunburn presents a risk of underlying long term damage to the skin. Abrasion processes often result in bleeding and pain and sometimes infection,
25 scabbing, and slight scarring. Laser treatments can result in pain and undesired burning, and if not applied properly can result in bleeding and scarring.

Acne and Seborrhea

Skin conditions such as acne and seborrhea are believed to be
30 caused or exacerbated by excessive sebum flow produced by sebaceous glands

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most of which are adjacent to and discharge sebum into, hair follicles. Sebum is composed of keratin, fat, and cellular debris. Sebum forms a moist, oily, acidic film that is mildly antibacterial and antifungal and may to some extent protect the skin against drying. The function of the sebum excretion in man is
5 controversial and it may very well serve no useful function whatsoever. It is known that the bacteria which cause acne is propionibacterium acne or (P-acnes). This bacteria grows in sebum. Significant sebum flow in humans begins at puberty. This is when acne problems arise. Males castrated before puberty do not develop acne or seborrhea.

10 Seborrhea is any of several common skin conditions in which there is an overproduction of sebum resulting in excessive oiliness or dry scales. Seborrhea includes seborrheic dermatitis (cradle cap, dandruff), seborrhea congestivea, seborrheic blepharitis, and seborrheic keratosis

Unwanted Hair

15 Removal of unwanted hair is a large business in the United States. Techniques include short term removal techniques such as shaving and plucking and long term (sometimes permanent) removal techniques such as electrolysis. Attempts have been made to use laser beams for hair removal. Prior art methods for permanent or long term hair removal are generally
20 painful and very time consuming.

Graphite Particles

It is known that graphite vaporizes at about 3,600°C. It is known that graphite is a strong absorber of infrared light and that infrared light such as the 1.06 micron laser beam produced by the Nd:YAG laser will penetrate
25 several millimeters through human skin.

What is Needed

What is needed is a simple quick treatment process which could be used to treat all of the above skin conditions.

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SUMMARY OF THE INVENTION

The present invention provides a very simple easily administered skin treatment process for (1) the removal of superficial epidermal skin cells in the human skin (2) the reduction or removal of unwanted hair and (3) the mitigation of skin conditions such as acne and seborrhea. A contaminant having a high absorption at at least one wavelength of light is topically applied to a section of the surface of the skin. A preferred contaminant is a mixture of 20% by weight of one micron graphite particles in mineral oil. Graphite is a very strong absorber of 1.06 micron light produced by the Nd:YAG laser. Portions of the contaminant are forced to infiltrate into spaces between the superficial epidermal cells, into hair ducts in the skin and into and/or adjacent to sebaceous glands. The skin section is illuminated with short laser pulses at the matching wavelength, so as to impact sufficient energy to the contaminant to cause explosion in the contaminant. The energy released in the course of the explosions may blow off layers of dead skin cells and/or destroy tissue responsible for hair growth and/or sebum production.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a skin section.

FIG. 2 is a block diagram.

FIGS. 3A-K demonstrate skin peeling.

FIGS. 4A-E demonstrates a hair removal.

FIGS. 5A-C demonstrates an alternative hair removal and acne treatment process.

FIG. 6 demonstrates a treatment wherein the hair is removed prior to application of contaminant.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the present invention can be described by reference to the drawings.

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Nd:YAG LASER AND CARBON PARTICLES IN OIL**Skin Peeling****Outer Layers of the Epidermis**

A first preferred embodiment of the present invention can be
5 described by reference to FIGS. 3 through 3J. FIG. 3A shows a typical cross
section of a section of the outer portion (the top three strata) of the human
epidermis such as that in the skin of a 50 year old female's cheek. Shown is a
representation of a 15-cell thick stratum corneum 1, and a 3-cell thick stratum
lucidum 2, and a 3-cell thick stratum granulosum. The total thickness shown is
10 about 100 microns (0.10 mm).

Individual cells of the stratum corneum have dimensions of about 10
to 15 microns long, about 5 microns wide and up to 2 microns thick. The cells
of the upper layers are loosely stuck together. Spaces between the cells range
from zero distance to about 1 or 2 microns.

15 Application of Carbon Solution

The first step of this preferred embodiment is to topically apply a
layer of carbon solution to the skin surface as shown in FIG. 3B. The solution
is comprised of 1 micron graphite powder in baby oil. The graphite-oil ratio is
20 percent graphite suspended in 80 percent oil by weight. The next step FIG.
20 3C, is to force some of the carbon particles down below the surface of the
stratum corneum. We prefer to do this with an ultrasound unit operating at
0.2 watts per cm² and 10 MHz.

We use a Hewlett Packard Model 3325A pulse generator and a
Parametrics transducer model A5525. We have found that approximately 5
25 minutes of ultra sound treatments at this frequency will force a significant
number of carbon particles down through several layers of the stratum
corneum. The result of the ultrasound treatment is shown in FIG. 3D. This
distribution of carbon particles has been demonstrated on pig skin.

Microscopic examination of biopsy samples from the pig skin show the
30 distribution depicted in FIG. 3D. As shown in FIG. 3D, two layers of graphite

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particles are left on the surface and a portion of the particles 6 are distributed below the surface.

Pulse Irradiation

The next step is to irradiate the skin surface with Nd:YAG laser pulses of about 3 J/cm² at a wavelength of 1.06 μ m. Pulse frequency is about 5 Hz but we scan the beam so that each location is subjected to pulses at a frequency of about 1 Hz. Graphite is very absorptive of laser energy at the 1.06 μ m wavelength. The latent heat of vaporization is about 10⁵ J/cm³ for cold solid graphite. (The energy required to heat room temperature graphite to the sublimation temperature is roughly 4% of the sublimation energy.) Thus, to vaporize a 1 micron cube (10⁻¹² cm³) would require approximately 10⁻⁷ J. The energy falling on the surface of the 1 micron particle (1 x 10⁻⁸ cm²) in a 3J/cm² pulse is 3 x 10⁻⁸ J, about one third of the energy needed to totally vaporize the particle. Therefore, a significant portion of the particle is vaporized. The energy is deposited in a few nanoseconds so there is no time for the heat to diffuse; therefore, the particle explodes violently upon being illuminated by the pulse. (Subsequent pulses will vaporize the smaller particles created by the earlier pulses.)

Thus, as a result of the first pulse 7 the first layer of graphite particles is exploded as shown at 8 in FIG. 3E. The second layer and the skin surface is effectively shielded from the first pulse 7 by the first layer. Some of the carbon particles above the skin have been pushed into the skin as a result of the shockwaves resulting from the explosion of the particle in the first layer. The second pulse 9 coming one second later, vaporizes the second layer as shown at 10 in FIG. 3F. As before, additional particles are pushed into the skin. The skin is fairly effectively shielded from pulse 9 by the second layer. But the third pulse 11 interacts with the skin and the carbon particle below the skin. Laser energy at a 1.06 wavelength has an extinction length in human skin of several millimeters but it is highly absorbed in the graphite particles below the surface and upon absorption of the energy from third pulse 11 as shown in

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FIG. 3G, the particles explode violently ripping off the dead cells of the stratum corneum which lay above the exploding cells all as shown in FIG. 3H. A few particles may be shielded from pulse 11 but three of four additional pulses 13 will assure that essentially all graphite particles are exploded as
5 shown in FIG. 3I.

FIG. 3J shows a cross section view of the skin surface after the laser irradiation. This drawing is based on pig skin biopsy results of skin treated as described above. The skin is washed lightly with an alcohol soaked cloth and allowed to dry resulting in a surface as shown in FIG. 3J. The depiction as
10 shown in FIG. 3J can be compared with that of FIG. 3A. We see that about three layers of the dead cells in the stratum corneum have been removed. We have observed similar effects on human skin tissue in connection with hair removal clinical experiments. For most patients, there is no pain, and no unpleasant feeling of heat. There is no significant injury to the skin tissue.
15 The Nd:YAG laser energy which was not absorbed in the carbon is harmlessly dissipated in the skin and tissue below the skin. It is preferable to provide a slight diverging beam to assure that it spreads after it hits the skin. In our preferred embodiment the spot size at the surface is 0.5 cm (diameter) and, before interacting with the skin, is spreading at 10 degrees.

20 Preliminary Biopsy Studies

Biopsy studies of both pig and human skin conducted six weeks after treatment confirm that there is no significant injury to the skin. Our preliminary conclusions from these studies indicate new collagen fiber formation in the upper part of the dermis immediately below the epidermal
25 basal membrane. These preliminary observations indicate an abundance of fibers which are long, wavy and bound together. There appears to be an increase in the portion of young collagen fibers in the samples. We also observe what appears to be an increase in plasmocytes and young fibrocytes. These preliminary observations indicate a positive effect of the treatment in
30 the upper layers of the dermis tissue. We have not yet developed an

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explanation for this indicated effect and we do not yet have sufficient experimental data to quantify the results.

Hair Removal

FIGS. 4A-4E demonstrate treatment of the skin for hair removal. In the process we use one of the same mixtures of one micron medical grade carbon (graphite) particles and mineral oil as we discuss above with respect to skin peeling. The composition is about 20% graphite by weight.

The hair in the to-be-treated is cut with a barber clipper to about a length of about 5 mm from the skin surface. The mixture is applied to the area to be treated. The mixture is massaged into the skin with a cotton swab until the hair ducts in the to-be-treated area are infiltrated to an estimated depth of about 20 microns to several millimeters. This stage of the process is depicted in FIG. 4A. In addition to the mixture infiltrated in the hair ducts, a thin film of the carbon-oil mixture (for example, about 100 particles per cm^2) is left on the surface of the skin in the area to be treated.

The area to be treated is then illuminated with a pulsed laser beam from a Nd:YAG laser. Preferred beam specifications are as follows:

20	Wavelength	1.06 micron
	Energy per pulse	1.5 Joules
	Beam area	$1/2 \text{ cm}^2$
	Energy density	3 J/cm^2
	Frequency	10 pulses per second

The beam is scanned over the area to be treated with each section of the skin in the area receiving about 5 pulses. The first or second pulses clean substantially all of the mixture from the skin surface by violently fracturing the carbon particles. By observing how many particles remain, the doctor can estimate the degree to which each area has been treated. As shown in FIG. 4A, the initial application of the carbon-oil mixture results in carbon particles being deposited about 20 microns deep in the duct. FIG. 4B represents the results of the first pulse shown in FIG. 4A. A shockwave in the mixture spreads out the mixture for several microns. More important, the

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violent fragmentation of the particles sends fragments through the duct. (FIG. 4C shows qualitatively the distribution of particles after about 2 pulses.) However, with each fragmentation, the particles get smaller (FIGS. 4D and 4E) and after about 4 or 5 pulses 30 through 36 the fragments have essentially
5 disappeared. Essentially all of the energy absorbed by the particles and fragments is transferred to the skin tissue surrounding the hair. The net result is depicted in FIG. 4E. The energy is sufficient to devitalize the tissue feeding the hair so the hair dies. In FIG. 4A through 4E arrow 38 locates the section of skin tissue damaged. Our biopsy tests indicate the thickness of the damaged
10 sections range from zero to about 20 microns. The damage to the tissue appears to be the combined result of both the heating effect of the hot carbon particles and oil and possibly some mechanical damage due to the kinetic energy of the particles and fragments.

We have had excellent results with our human tests. In an early
15 experiment with this improved process on my own leg essentially all hair was removed and after 24 months there has been no significant regrowth. Our clinical trials with facial hair have been on-going for 24 weeks. We have been very conservative in the application of the laser beam, but the results are very good. No significant short term injury to the skin has been observed (only
20 minor redness and in a very few cases some very minor bleeding). No long term injury has been observed. Hair removal success ratio in the treated area has ranged from about 0% to about 90% with the average being about 60%.

Treatment for Acne and Seborrhea

Our preferred process for treatment of acne and seborrhea is
25 basically the same as the treatment for hair removal and skin peeling. The import difference being the section of skin treated is one in which the patient has had problems with acne or seborrhea. Preferably, the treatment is scheduled when the ducts to over active sebaceous glands are open. The carbon solution described in the preceding section is applied and caused to
30 infiltrate into the duct leading to the sebaceous glands as shown in FIG. 5A.

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The portion of the sebaceous glands is also shown in FIG. 1. Laser illumination is substantially the same as for hair removal. The carbon particles within or in the vicinity of the sebaceous glands are heated to vaporization temperatures which causes the particles to fracture violently or vaporize.

- 5 Energy released in the process results in full or partial destruction of epithelium tissue making up the surface of the inside wall of the sebaceous glands which tissue, produces the sebum. This results in either death or reduced effectiveness of the sebaceous glands in the section of skin treated. The consequence is a reduced sebum production. The consequence of reduced
- 10 sebum production is reduced levels of acne and seborrhea.

CONFINEMENT OF PARTICLES

- Another preferred embodiment for skin treatment is the same as the first preferred embodiment except that after the carbon-oil suspension is placed on the skin surface, a thin flat piece of glass (such as a microscope
- 15 glass) is placed firmly over the suspension in order to confine the small explosions. Several pulses (preferably about 1 or 2) of the laser beam are applied through the glass onto each section of suspension. The effect is to greatly enhance the subsurface contamination of the upper layers of the epidermis with small particles of graphite. The effect is shown in FIGS. 3K
- 20 and 3L. One or two pulses is sufficient to produce substantial subsurface contamination with small carbon particles. After this application the glass is removed and the process as explained above for the first embodiment is continued until essentially all of the graphite has been vaporized. In an
- 25 alternate embodiment a disposable plastic plate, transparent to the laser beam could be used instead of the glass plate. The disposable plastic plate could be made a part of an articulated arm of the laser or a part of a hand piece attached to the articulated arm.

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CO₂ LASER

A third preferred embodiment utilizes a CO₂ pulse laser. Preferred operating parameters are: wavelength 10.6 micron, energy density per pulse 2.5 Joule/cm², pulse diameter 1 cm, pulse duration 50 ns. Laser beams at 10.6
5 micron have an extinction length in skin of about 40 micron because the pulse energy is highly absorbed in water. It is much more highly absorbed in carbon. We estimate an extinction length of 1 to 2 microns.

The process is very similar to that described above. Graphite is applied as above using the ultrasound to force some of the carbon below the
10 surface. The laser pulses are applied as above and to the first two pulses produce similar results cleaning off the two layers of carbon. The third pulse however will in addition to vaporizing carbon below the skin surface will vaporize a thin surface of tissue. Therefore, we get the combined effect of (1) mechanical removal of tissues due to the explosion of particles below the
15 surface and (2) vaporization of a surface layer of epidermal tissue about 2-3 microns thick.

LIQUID CONTAMINANT

Instead of the carbon oil mixture discussed above, we could use other liquids or suspensions such as India ink. India ink is comprised of very
20 small submicron graphite particles suspended in a liquid such as a water solution of alcohol. We may also use a solution of warm water colored with black food coloring at one part color per fifty parts water. Apply to skin surface with gauze for 10 minutes. The contaminant will infiltrate into the space in the upper layers of the corneum stratum. (These spaces are normally
25 filled with air.) Remove gauze and illuminate with about 1 or 2 pulses per site using a CO₂ laser operating at 10.6 microns and 50 nanosecond duration pulses with an energy density of 2 Joules per cm². These short pulses will deposit sufficient energy selectively to the contaminant solution to vaporize instantly the contaminant tearing off the upper most corneum stratum cells in the skin
30 section.

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An alternative to this embodiment is to add indocyanine green to the warm water instead of the black food coloring. Indocyanine green absorbs infrared light such as that produced by the Nd:YAG, CO₂, Alexandrite, Ti:Sapphire and Ga:As diode lasers. Since water is an excellent absorber of CO₂ laser energy, many water based skin lotions could be used with the CO₂ laser.

REMOVAL OF HAIR (PARTIALLY OR FULLY) FROM DUCT

A preferred embodiment of this invention for hair removal and for acne treatment is shown in FIGS. 5 A, B and C and 6. FIG. 5A depicts 2 hairs on a skin section showing hair stem 33, hair duct 31 and the sebaceous gland 38. As shown in FIG. 5B the hair is partially removed from the hair duct below the skin surface by chemical depilation. The carbon solution is then applied to the skin section and rubbed into the skin. In this case, since the upper part of the 50 micron diameter hair is gone, there is much more room in the duct for the solution with 1 micron particles as shown in FIG. 5C. The skin section is illuminated as discussed above but in this case the process is much more effective for hair tissue destruction and sebaceous gland tissue destruction because there is a far greater quantity of carbon particles initially in the duct.

FIG. 6 shows a hair duct in which the complete hair has been completely removed by a method such as plucking or by extraction with hair extraction wax. Here an even greater quantity of carbon particles can be infiltrated into the duct for even more effectiveness. A good method of removing the hair in preparation for the laser treatment is as follows:

Place a thin layer of super glue on a 2 cm² section of a glass microscope slide. After five seconds place the treated section of the slide on the skin area to be treated. Leave on the skin for 30 seconds. Lift the slide. This will pull out all hairs by the roots. The ducts can then be infiltrated with contaminant as discussed above.

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OTHER EMBODIMENTS

Persons skilled in the laser-medicine art will recognize that many other lasers-contaminant combination could be used to practice this invention.

The important attributes of the combinations are:

- 5 1) The contaminant must be very highly absorptive of energy at the wavelength of the laser beam when using small particles, the particles preferably should be smaller than 10 microns.
- 2) The laser beam preferably is a pulsed beam with very short pulses (pulse duration of less than 1 microsecond).
- 10 3) The contaminant should be capable of being infiltrated into spaces in the upper layers of the skin.
- 4) The contaminant should explode with sufficient energy upon absorption of the laser energy to produce the desired results.

Applicants have tested acrylic tattoo inks which have been approved
15 by FDA for tattoo use. Black and blue tattoo inks marketed by Spaulding and Rogers appear to work well with a Nd:YAG laser operating at 1 Hz, 1.06 micron with an energy density of about 3 J/cm². We had less success with other colors. Applicant has also performed experiments using black powder which is a very finely ground mixture of potassium nitrate, carbon and sulfur.
20 This mixture explodes chemically when illuminated with 10 ns, 2 J/cm² Nd:YAG laser pulses. The portions of the above chemicals in black powder may be about 75% KNO₃, 15% carbon and 15% sulfur.

.....
While the above description contains many specifications, the reader
25 should not construe these as limitations on the scope of the invention, by merely as exemplifications of preferred embodiments thereof. Those skilled in the art will envision many other possible variations are within its scope. Accordingly the reader is requested to determine the scope of the invention by the appended claims and their legal equivalents, and not by the examples
30 which have been given.

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We claim:

1. A skin treatment process comprising the steps of:
 - a. topically applying to a section of skin a contaminant having a high absorption at at least one frequency band of light which penetrates outer
5 layers of human epidermis,
 - b. forcing some of said contaminant to infiltrate into spaces in the skin and
 - c. illuminating said section of skin with pulses of said at least one frequency band of light, so as to impart to the contaminant sufficient
10 energy to cause at least a portion of said infiltrated contaminant to explode.
2. A process as in Claim 1 wherein said contaminant comprises a large number of carbon particles.
3. A process as in Claim 1 wherein an ultrasound device is utilized to force said some of the small carbon particles to infiltrate into said
15 spaces.
4. A process as in Claim 1 wherein an explosion, defining a forcing explosion, of a portion of said contaminant is utilized to force another portion of said contaminant to infiltrate into said spaces.
5. A process as in Claim 1 wherein a confinement means,
20 transparent to said at least one frequency band of light is placed firmly over said topically applied contamination for the duration of said forcing explosion for the purpose of confining said forcing explosion.
6. A process as in Claim 5 wherein said confinement means is a glass plate.
- 25 7. A process as in Claim 5 wherein said confinement means is a plastic plate.
8. A process as in Claim 7 wherein said plastic plates is a part of an articulated arm.

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9. A process as in Claim 1 wherein said small carbon particles are small graphite particles.

10. A process as in Claim 9 wherein said small graphite particles are mixed with an oil.

5 11. A process as in Claim 10 wherein said oil is baby oil.

12. A process as in Claim 2 wherein said small carbon particles have major dimension of about 1 micron.

13. A process as in Claim 2 wherein said laser pulses are pulses from a Nd:YAG laser.

10 14. A process as in Claim 2 wherein said laser pulses are pulses from a CO₂ laser.

15. A process as in Claim 1 wherein said spaces in said skin comprise spaces in hair ducts in said skin not occupied by hair.

15 16. A process as in Claim 15 wherein said at least one of said pulses has sufficient energy to destroy tissue feeding hair growing in said hair ducts.

17. A process as in Claim 15 comprising the additional step of removing from said ducts a portion of a plurality of hairs in said skin section prior to applying said contaminant.

20 18. A process as in Claim 15 comprising the additional step of removing from said ducts substantially all of a plurality of hairs in said skin section prior to applying said contaminant.

19. A process as in Claim 1 wherein said spaces in said skin comprises spaces between superficial epidermal skin cells.

25 20. A process as in Claim 1 wherein said spaces in said skin comprises spaces within sebaceous glands.

21. A process as in Claim 2 wherein said spaces in said skin comprise spaces adjacent to sebaceous glands.

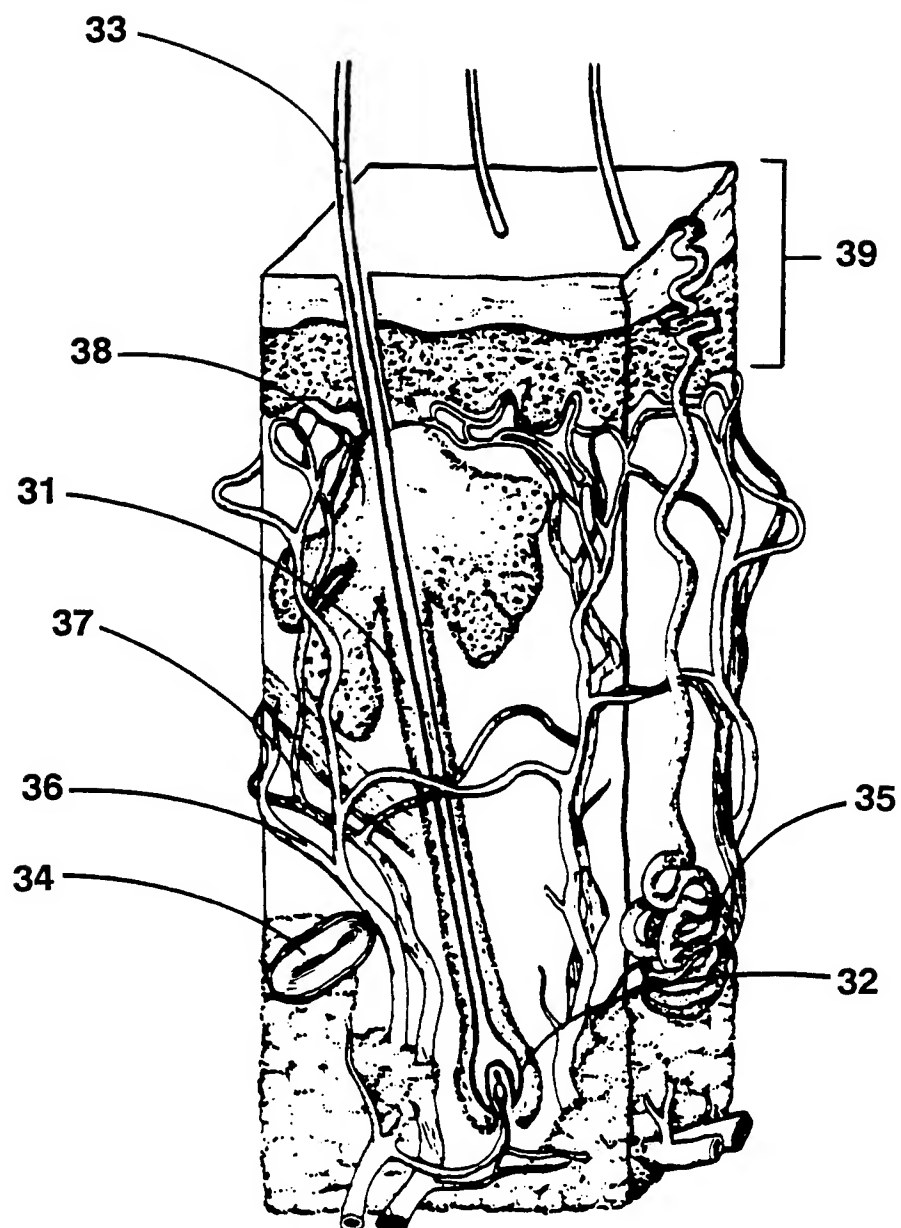
30 22. A process as in Claim 1 wherein said contaminant is a chemical explosive.

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23. A process as in Claim 1 wherein said contaminant is black powder.

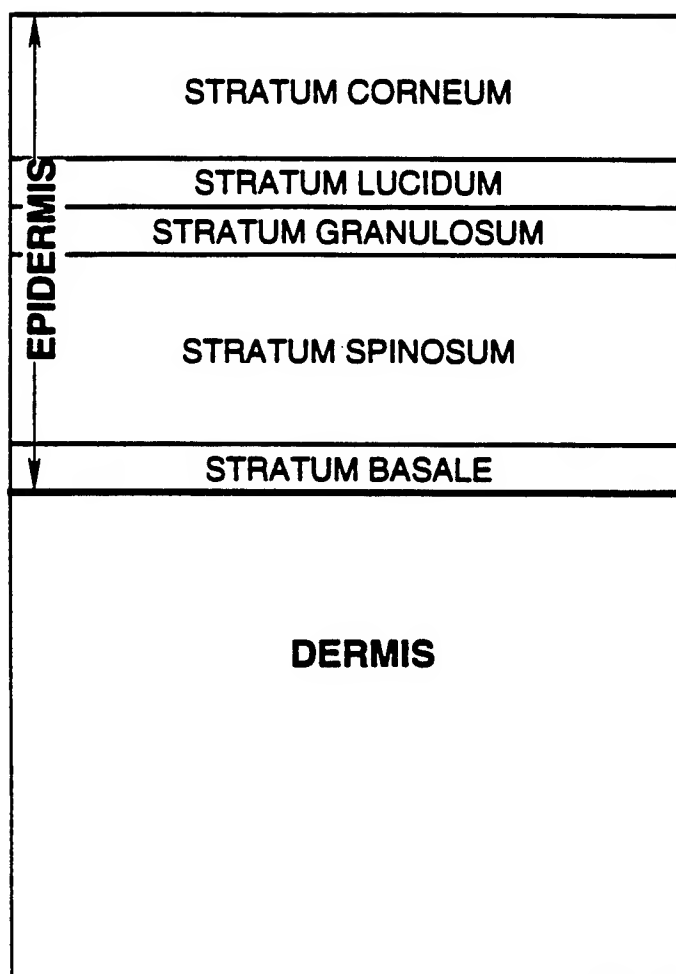
24. A process as in Claim 1 wherein said contaminant is a mixture of potassium nitrate, carbon and sulfur.

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**FIG. 1**

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**FIG. 2**

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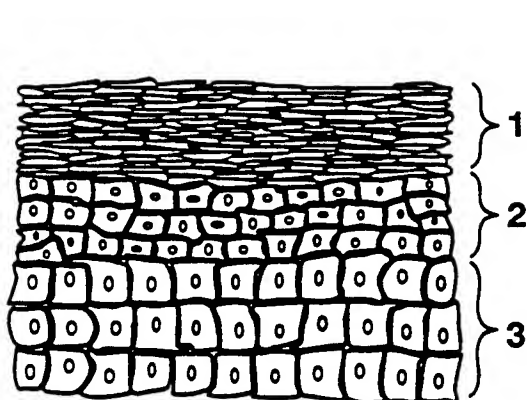


FIG. 3A

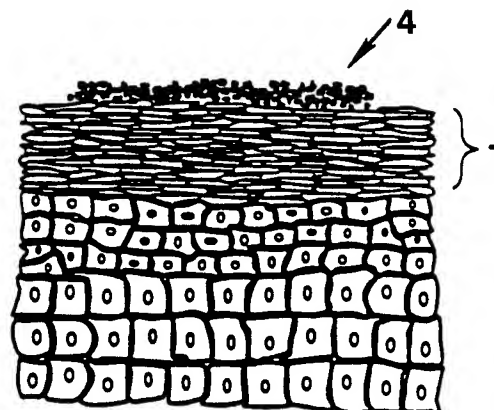


FIG. 3B

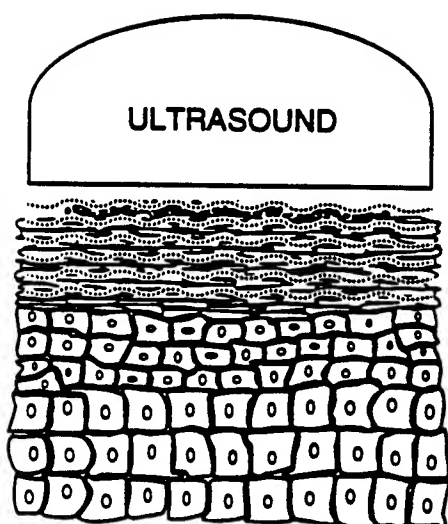


FIG. 3C

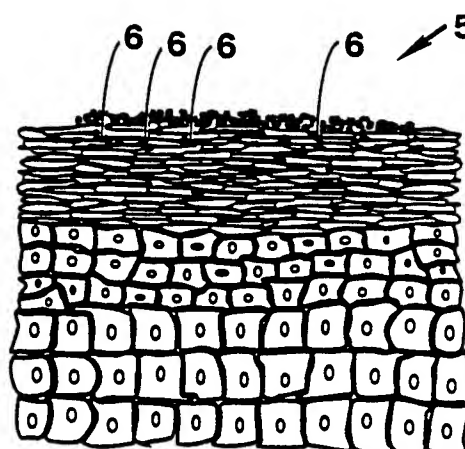


FIG. 3D

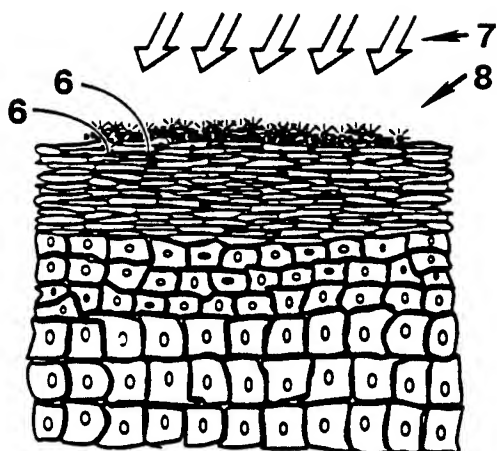


FIG. 3E

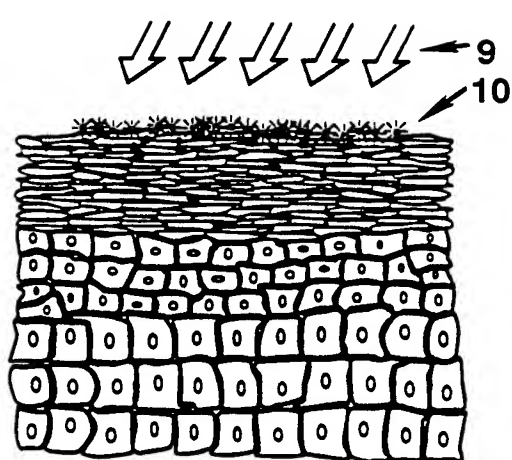
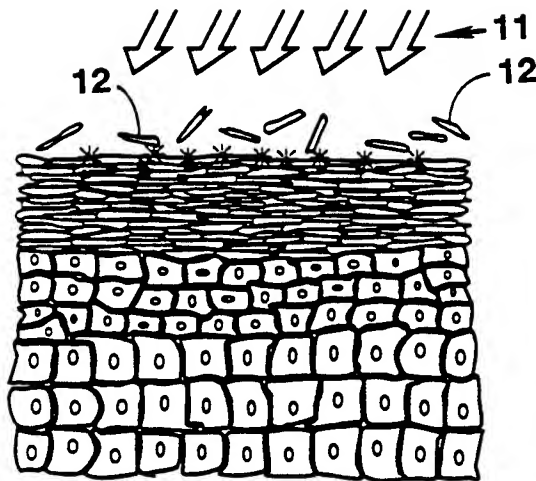
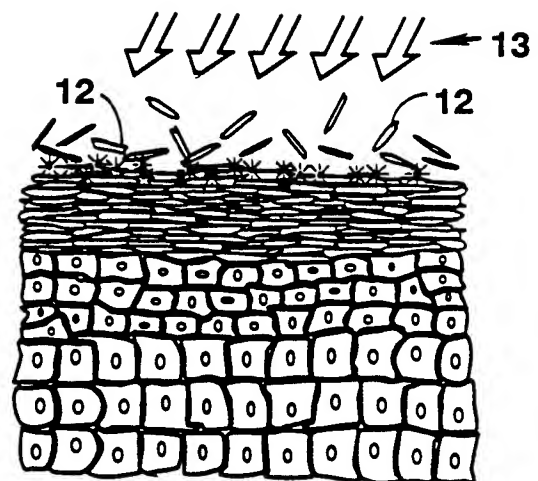
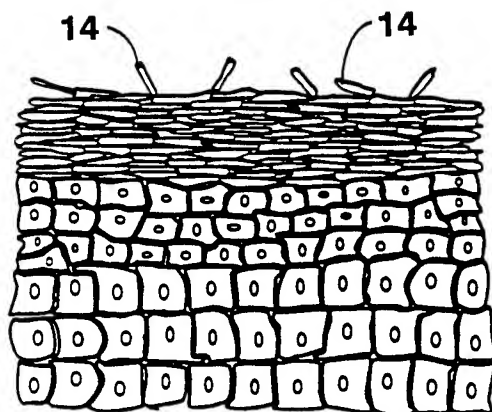
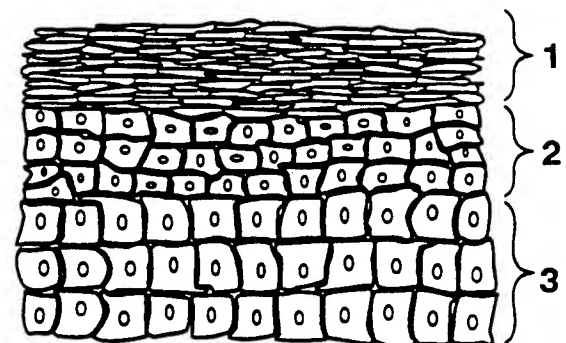


FIG. 3F

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**FIG. 3G****FIG. 3H****FIG. 3I****FIG. 3J**

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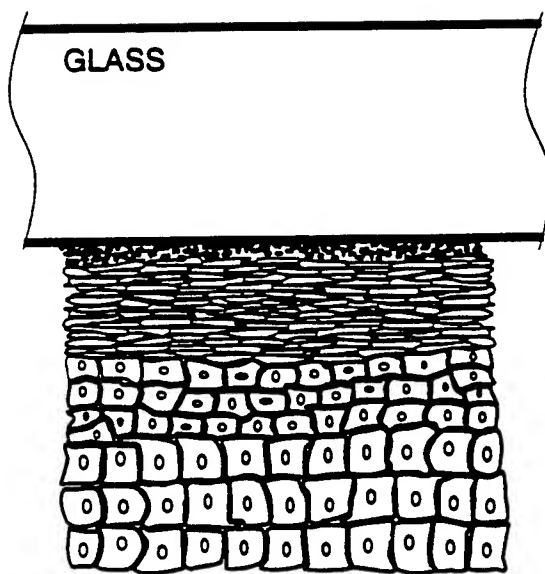


FIG. 3K

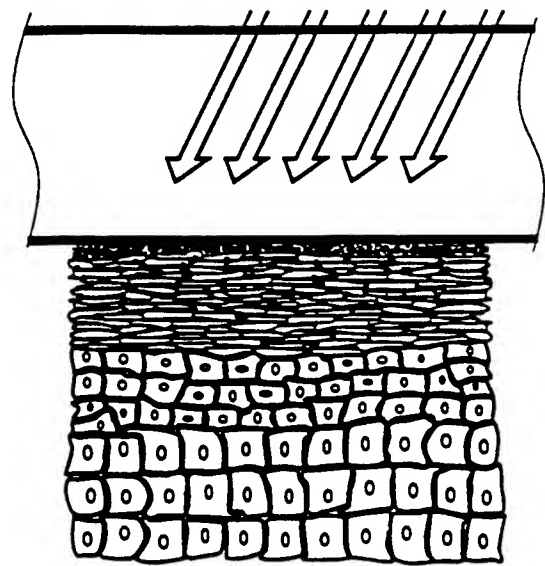


FIG. 3L

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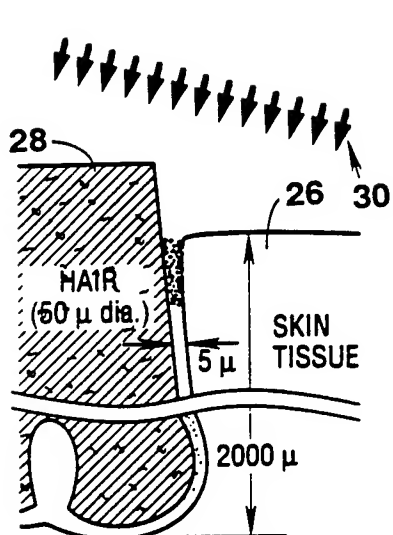


FIG. 4A

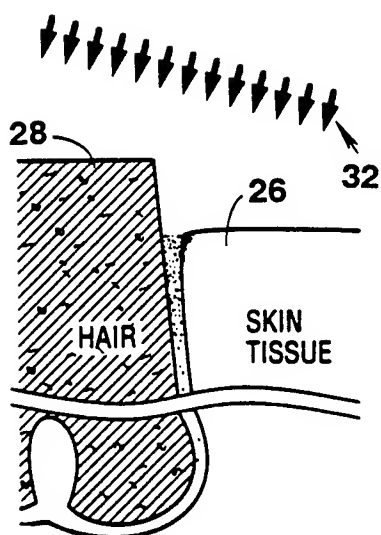


FIG. 4B

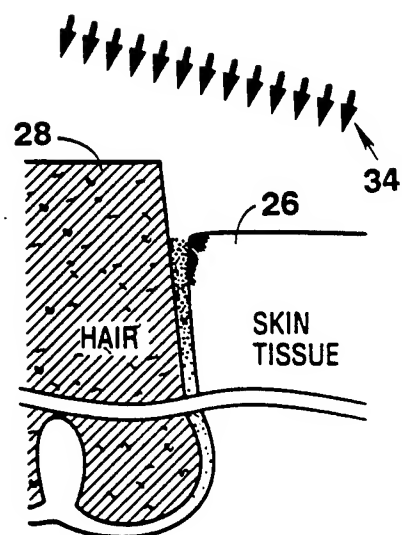


FIG. 4C

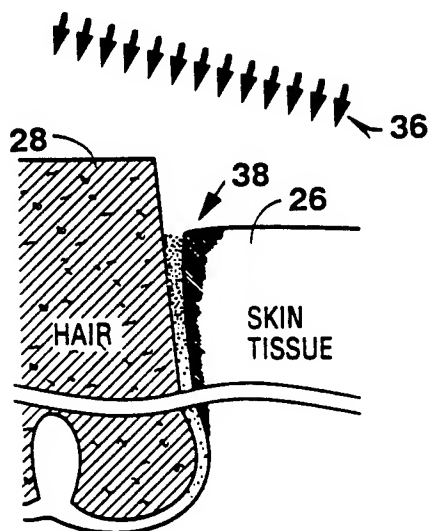


FIG. 4D

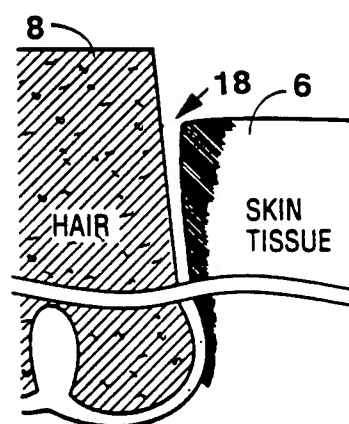
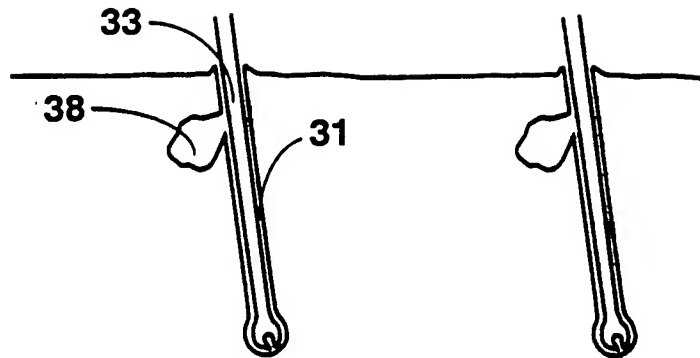
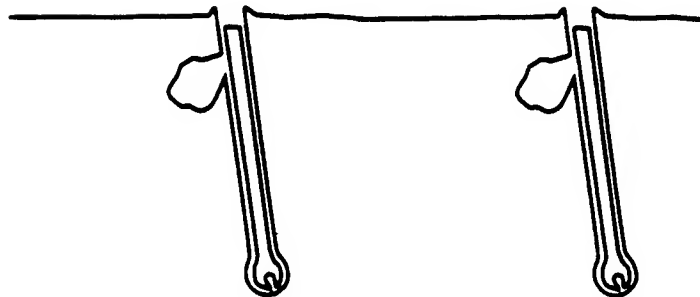
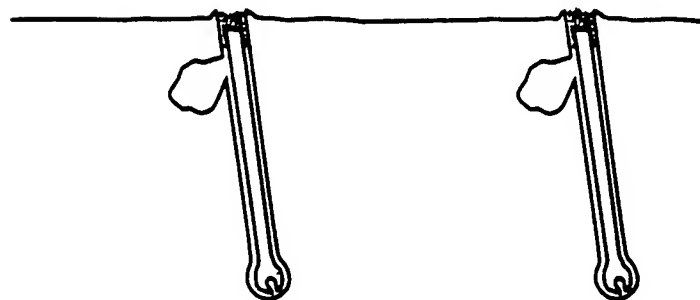


FIG. 4E

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**FIG. 5A****FIG. 5B****FIG. 5C**

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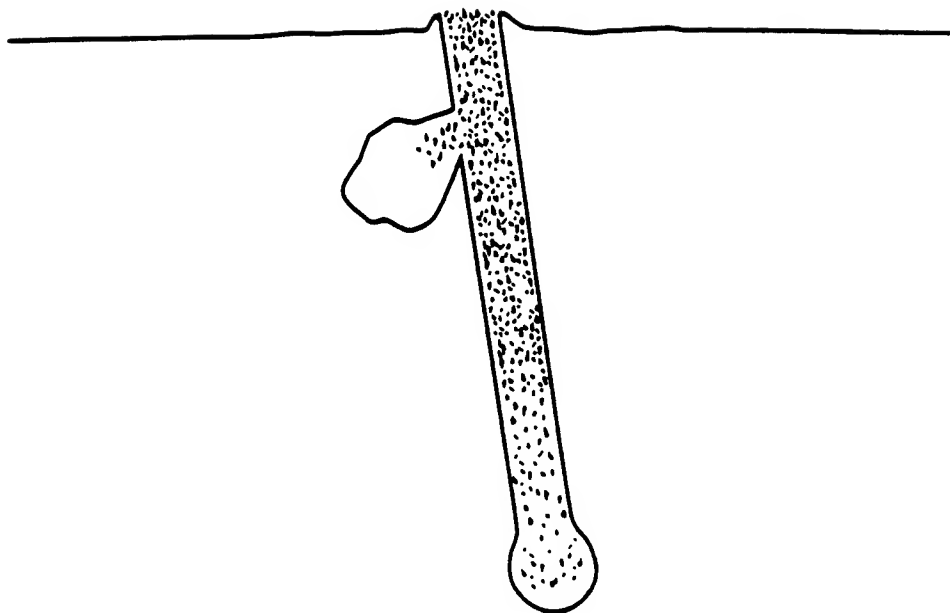


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/10155**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 17/36

US CL :606/9

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/898; 606/9, 131

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 3,769,963 (GOLDMAN ET AL.) 06 November 1973, see entire document.	1-24
A	US, A, 5,059,192 (ZAIAS) 22 October 1991, see entire document.	1-24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z*	document member of the same patent family
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P document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

25 JULY 1996

Date of mailing of the international search report

15 AUG 1996

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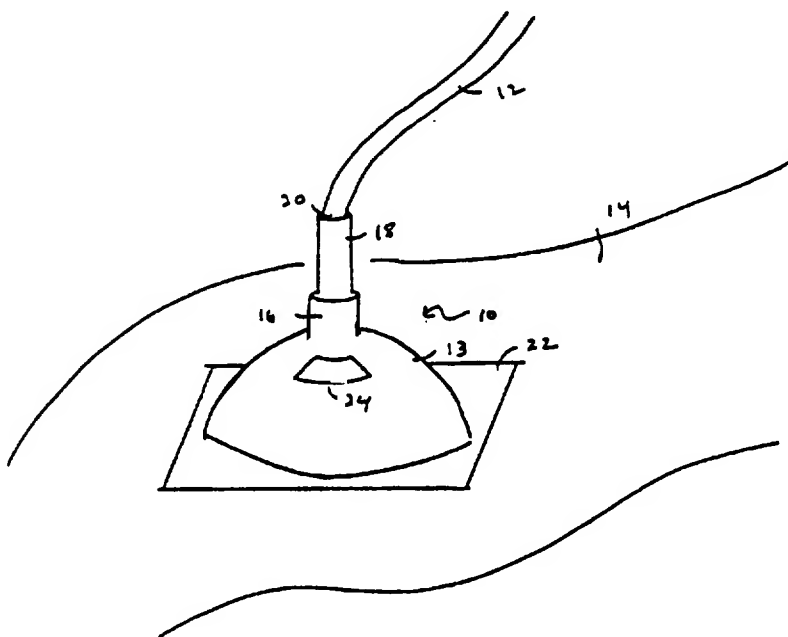
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(54) Title: RADIATION-DELIVERY DEVICE



(57) Abstract

A method and apparatus (10) for irradiating material (14), such as tissue in a patient, is described. The method features the step of first exposing the tissue (14) with a radiation. Following the exposing step, the radiation is partially re-emitted (e.g., reflected or scattered) from the tissue (14). The re-emitted radiation is then collected and imaged back onto the tissue (14) using an external irradiating device (13), containing, for example a hemispherically shaped reflective housing (13). The housing contains a reflective coating (30) disposed on one of its surfaces.

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RADIATION-DELIVERY DEVICE

Background

This invention relates to radiation-delivery
5 devices.

Radiation sources, such as lasers, are used in a variety of medical applications because of their ability to generate precise, self-cauterizing incisions and locally heat tissue without contacting the patient. In
10 particular, laser light is used in a variety of dermatological therapies, such as to remove tatoos, port-wine stains, and unwanted hair. In these applications, radiation is typically delivered through a fiber optic system to a lens, which subsequently images the radiation
15 onto the region of interest. The radiation is absorbed by a portion of the skin or hair (e.g., the melanin or blood vessels), resulting in optical absorption and localized heating.

In nearly all laser-based surgical procedures, it
20 is desirable to maximize the amount of radiation delivered to the tissue, and minimize the amount of radiation which is re-emitted (e.g., reflected or back-scattered) from the tissue. This is particularly difficult to achieve during dermatological procedures, as
25 the turbid optical quality of the skin tends to scatter incident light in all directions. In addition, reflection due to differences in the refractive indices of the skin ($n = 1.5$) and the air ($n = 1.0$) leads to further losses. To compensate for radiation lost through
30 these processes, the operator is forced to increase the output power of the light source. This often decreases the accuracy of the procedure, or may, in fact, be impossible if the light source is operating at its maximum power output.

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Several references teach optical systems which manipulate laser beams to generate more desirable light fields for medical therapies. In U.S. Patent 5,309,339, for example, Webb describes an optical concentrator for
5 manipulating the cross-sectional area and reducing speckle of an incident laser beam. In Webb's device, a spherical or hemispherical mirror is used to return laser light scattered from a diffusely reflective surface back onto the point of incidence. Lenses are then used to
10 produce an output beam by collecting light from the point of incidence.

Summary

In general, in one aspect, the invention provides a method for irradiating a material. The method includes
15 the step of first exposing the material with radiation (e.g., optical radiation). Following the exposing step, radiation is partially re-emitted (e.g., scattered, reflected, or both scattered and reflected) from the material. The material is then re-exposed with the re-
20 emitted radiation. Preferably, the material is a patient's tissue. By "tissue" is meant any collection of cells or any specific organ in the patient (e.g., human skin).

The method of the invention is carried out with an
25 irradiating device configured receive radiation from a radiation delivery means. The radiation delivery means delivers radiation from a radiation source to the material, and is preferably connected to a reflective housing. The housing includes an opening or surface for
30 placement over the material and a reflective component proximal to the opening or surface. Most preferably, the radiation delivery means is a fiber optic waveguide or an articulated arm, and the radiation source is a laser.

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In preferred embodiments, the re-emitted radiation is received and reflected by a reflective device to re-expose the material. For example, the reflective device can be a reflective housing positioned proximal to the material prior to the exposing step. Preferably, the reflective housing is substantially hemispherical in shape, and the material is positioned substantially near the center of the hemisphere. Alternatively, the reflective housing is substantially elliptical in shape, and the material is positioned substantially near a focus of the ellipse. The reflective housing may also be substantially spherical in shape, with the opening disposed on a surface of the sphere. In still other embodiments, the reflective housing is substantially cone-shaped and includes an opening at the base of the cone. During operation, the material is positioned near this opening.

The method of the invention can also be carried out with an irradiating device which includes an optically transparent plate featuring a reflective coating on one of its surfaces. The reflective coating is disposed on the plate to transmit normally incident radiation (i.e., radiation angled at between about 80° and 100° relative to the surface of the reflective coating), receive radiation re-emitted from the material, and reflect any re-emitted radiation back onto the material. Preferably, the reflective coating contains a dielectric material or multiple layers of dielectric materials which exhibit angularly dependent reflective properties.

Here, by "substantially hemispherical", "substantially elliptical", or "substantially spherical" is meant a reflective housing which is shaped, respectively, in the form of a hemisphere, ellipse, or sphere so that it reflects incident light to a well-

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defined area. Preferably, this area is not more than a few millimeters in radius. "Substantially cone-shaped" means at least a portion of the housing is conically shaped. By "center of the hemisphere" is meant the
5 geometrical center of the sphere composed of two identical hemispheres. By "substantially near the center" or "substantially near the focus" is meant a position within a few millimeters of, respectively, the actual center or focus. "Substantially transparent" and
10 substantially reflects" means that, respectively, at least 80% of the radiation is either transmitted or reflected.

The reflective housing preferably includes a reflective coating for reflecting the re-emitted
15 radiation. The coating, for example, may be a reflective film, such as a metallic or dielectric film. The dielectric film may be reflective in only a portion of the electromagnetic spectrum, thereby allowing direct visualization of the material through the film.

20 In other preferred embodiments, the reflective housing features an array of grooves configured to reflect the re-emitted radiation. These grooves have reflective properties similar to those of corner cubes, retroreflectors, or similar optical components which
25 reflect radiation by internal reflection. Other reflecting materials, such as white paint or reflecting tapes, may be used to reflect radiation within the housing. In these embodiments, the reflective housing may take on any shape. For example, in addition to the
30 embodiments described above, the housing may be formed in the shape of a cylindrical tube, with the reflective material disposed on portions of the tube's inner surface. In this case, the opening for irradiating the tissue is positioned on one of the flat surfaces of the
35 tube.

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In preferred embodiments, the irradiation device is used during a medical therapy to irradiate a patient's tissue. In this case, the device is used in combination with standard medical procedures normally employed when
5 radiation is delivered to tissue. Preferably, the radiation used in the therapy is optical radiation, and the therapy is used to treat human skin. Examples of such therapies include optical removal of tatoos, port-wine stains, abnormal blood vessels, psoriatic skin,
10 unwanted hair, pigmented lesions, skin cancers and other lesions treated by laser surgery, phototherapy, photochemotherapy or photodynamic therapy.

The invention has a number of advantages. In particular, it increases the efficiency of a laser-based
15 surgical procedure by treating the tissue of interest with radiation which is normally not utilized. Scattered or reflected light, lost during conventional procedures, is effectively "recycled" and used to re-expose and treat the tissue. In this way, optical fluences can be kept
20 relatively low during treatment, thereby enhancing the accuracy and flexibility of the therapy.

The invention provides a gain of optical energy available to the tissue by a factor of up to $(1-R)^{-1}$, where R is the wavelength-dependent fraction of incident
25 light re-emitted from the tissue. For example, when R is 0.7 (a typical value for red light re-emitted from fair skin) the energy available to the skin using the irradiation device may be as large as three times that available without the device.

30 In addition to increasing the amount of radiation available for therapy, the invention can also effectively increase the exposure spot diameter of the radiation. In many applications in which the "target" for therapy is deep within the skin (e.g., during the removal of

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tattoos, port-wine stains, or hair), such a larger exposure spot diameter is advantageous.

Moreover, by collecting and then re-exposing the tissue of interest with the re-emitted radiation, the invention generates a more spatially uniform field during therapy. This gives the operator more control over the amount of heat delivered to the tissue, and thus improves the accuracy of the therapy.

The invention also increases the safety of laser-based therapies. Light reflected or scattered from the tissue, as well as ablated tissue which can be hazardous to the operators, is contained within a well-defined area by the irradiating device. Moreover, the device can be made small and compact, and can be used interchangeably with conventional laser-based surgical instruments. The device can additionally be fabricated with relatively inexpensive, disposable materials; a new, sterilized device can therefore be used for each procedure.

These and other advantages will be apparent from the following detailed description, and from the claims.

Brief Description of the Drawings

Fig. 1 is a top view of an irradiating device of the invention being used to irradiate a patient's skin;

Fig. 2 is a cross-sectional side view of an irradiating device in contact with the patient's skin;

Figs. 3A-3C are, respectively, cross-sectional side views of the irradiating device during initial irradiation of the skin, after radiation is initially re-emitted from the skin surface, and after the re-emitted radiation is reflected off the reflective housing and back towards the skin surface;

Figs. 4A and 4B are cut-away cross-sectional side views of, respectively, a reflective housing including a

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radiation-reflecting coating, and a reflective housing including an array of retro-reflecting grooves;

Fig. 5 is a cross-sectional side view of an irradiating device including a reflective housing
5 featuring a hemispherical top portion and a tapered bottom portion;

Fig. 6 is a cross-sectional side view of an irradiating device containing a reflective housing featuring two hemispherical top portions and a straight
10 bottom portion;

Fig. 7 is a cross-sectional side view of an irradiating device containing an elliptical reflective housing;

Fig. 8 is a cross-sectional side view of an irradiating device including a cone-shaped reflective housing; and,

Fig. 9 is a side view of a irradiating device featuring a flat, optically transparent plate coated with a reflecting dielectric film.

20 Detailed Description

Device Structure

Referring first to Fig. 1, an irradiating device 10 delivers radiation during a therapy to an area of a patient's tissue 14. The device 10 is configured so that
25 radiation which is normally re-emitted from the tissue after irradiation (and is thus wasted during the therapy) can be collected and imaged back onto the originally irradiated area.

The device includes a fiber optic waveguide 12
30 coupled to a laser or other radiation source (not shown in the figure). A distal end 20 of the fiber optic waveguide is housed in a delivery handpiece 18 and an input port 16 so that radiation from the fiber can be delivered to the device 10. The input port 16 is

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connected to a hemispherically shaped reflective housing 13 which surrounds the tissue to be irradiated and is configured to reflect radiation. During operation, radiation is delivered from the fiber optic waveguide 12 to the tissue. Portions of the delivered radiation are either absorbed by the tissue, leading to radiation-induced heating, or are re-emitted from the irradiated area. The re-emitted radiation propagates away from the tissue, and is collected by the hemispherically shaped reflective housing 13. A template 22 connected to the housing 13 is used to position the device on the patient's tissue and facilitate alignment of the radiation. The template is especially useful for aligning radiation onto tissue containing rough or curved surfaces, such as the skin. The reflective housing 13 includes a transparent porthole 24 for viewing the irradiated region.

Figs. 2, 4A and 4B show cross-sectional views of the irradiation device 10 and the reflective housing 13. The delivery handpiece 18 and input port 16 connected to the housing each enclose portions of the fiber optic waveguide 12. The distal end 11 of the waveguide 12 extends into the device and is surrounded by the hemispherically shaped reflective housing 13. The housing 13 is connected to the template 22 which, in turn, is placed in contact with a patient's tissue 14. The template 22 includes an opening 21 positioned above a portion 17 of the tissue and in the center of the hemispherical reflective housing. The opening 21 and distal end 11 of the waveguide are aligned so that, during therapy, radiation from the waveguide passes through the template and onto the tissue.

The reflective housing includes a reflective coating 30 on its inner surface so that during therapy radiation scattered or reflected from the tissue is

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collected and imaged back onto the originally irradiated portion of tissue. The reflective coating 30 can be any reflective material and can be made using any of a number of techniques known in the art. For example, the coating
5 may be deposited as a thin reflective film on the inner surface of a transparent substrate 32. The coating may also be deposited on the substrate's outer surface.

In particular embodiments, the coating may be a thin metallic film composed of materials such as
10 aluminum, silver, or gold. The reflective properties of these materials are dependent on the material composition and the film thickness, and are well known in the optical arts. Dielectric films may also serve as reflective
15 reflectivities at visible and infrared wavelengths, and can be used to coat the inner or outer surfaces of the substrate material 32. Dielectric coatings have the additional advantage that they can be made transparent to visible wavelengths or radiation at certain angles of
20 incidence; thus, when used with transparent substrates, these materials allow the operator to directly view the procedure without the need for a porthole.

The reflective housing is preferably shaped so that re-emitted radiation is collected and imaged onto a
25 region contained in the originally irradiated area. In this way, the spatial extent of the irradiated area is not significantly increased by the reflective process, and thus the accuracy of the procedure is maintained. This is particularly important during therapies requiring
30 small radiation spot sizes, such as during the treatment of small vascularized regions in human skin. As described above, the housing preferably has a hemispherical shape, and the irradiated region is located as close as possible to the center of the hemisphere. In
35 this configuration, the re-emitted radiation incident on

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the tissue is evenly distributed, and "hot spots" in the irradiated area are avoided.

In the embodiment shown in Fig. 4A, the reflective housing is hemispherical, and radiation (indicated by the
5 arrow 33) incident on the coating 30 is reflected back towards the tissue (arrow 34) with a slight angular deviation. This angle is such that the re-exposed region of tissue lies substantially within the originally exposed area. When the coating 30 is deposited on the
10 outer surface 35 of the substrate 32, radiation reflected back towards the tissue propagates through the substrate twice before re-exposing the tissue.

Referring now to Fig. 4B, the housing can also be made reflective by cutting right-angle grooves 36 into
15 the transparent substrate 32. In this case, each groove 36 has two orthogonal reflective faces 35a, 35b and serves as an individual "corner cube" or "retroreflector" for reflecting the incident radiation. Preferably, an array of concentric grooves, each positioned at different
20 cross-sectional slices of the hemisphere, are cut into the substrate. Other patterns of grooves may also be used. Preferably, in order to maximize the reflectance of the housing, the grooves are spaced together as closely as possible. For total internal reflection to
25 occur at the air/substrate interface 38 of each groove, the substrate must be composed of a material having the appropriate refractive index. Typically, optically transparent materials, such as glasses or plastics having refractive indices greater than 1.4, are suitable. In
30 the reflective housing 13 shown in Fig. 4B, incident radiation (indicated by the arrow 40) re-emitted from the tissue is reflected back towards its point of origin. The reflected radiation (arrow 42) is displaced by an amount equal to the propagation distance between the two
35 orthogonal faces 35a, 35b of the groove. In this way,

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the irradiated area of tissue is kept small. Moreover, in the embodiment shown in Fig. 4B, the radiation is reflected by the grooves directly back towards its point of origin regardless of the shape of the reflective housing. Thus, irradiation devices employing reflecting grooves have the additional advantage that they can be formed into arbitrary shapes. This is particularly desirable for irradiating devices configured to irradiate hard-to-reach areas of tissue.

10 Preferably, in the embodiments described above, the substrate is composed of a material which is transparent to the incident radiation. For example, for visible radiation, the substrate can be composed of transparent glasses, plastics, or other suitable materials known in the art. In particular, plastic materials are desirable, as they can be manufactured in high quantities for relatively low costs. Such materials are formed using techniques well-known in the art, such as injection molding or machining. Irradiation devices, and particularly those made from plastic materials, can be sterilized and are disposable.

In addition to the reflective surfaces shown in Figs. 4A and 4B, other reflective coatings and devices known in the art can be used with the irradiation device's reflective housing. For example, the substrate can be substantially composed of a reflecting material, thereby obviating the need for inner or outer surface coatings. In particular embodiments, the substrate can be composed of a diffusely reflecting white plastic, frosted glass, or a related material. These materials have lower reflectivities than metallic or dielectric-coated materials, and function essentially as optical "integrating spheres." Materials of this type have the advantage of irradiating an area with a particularly

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uniform field after reflecting the re-emitted radiation.

In other embodiments, the reflecting housing may be covered on its inner or outer surface with reflecting tape, paint, or any other material which can be used to reflect radiation, and particularly optical radiation. Preferably, the reflecting material reflects at least 80% and most preferably, at least 90% of the remitted radiation. Since the most preferred applications involve the use of optical radiation, the coating preferably exhibits the above-mentioned reflectivities for wavelengths in the range of 200 nm to 5 microns. In particularly preferred embodiments, the reflective housing is configured to reflect optical wavelengths which are typically used in dermatological applications, i.e., 500 - 1100 nm.

In still other embodiments, the template connected to the housing can be replaced with a plate which is transparent to the incident radiation. Like the template, the transparent plate is used to position the device on the patient's tissue and facilitate alignment of the radiation. The plate is particularly effective in aligning radiation onto tissue containing rough or curved surfaces, such as the skin.

Figs. 3A-3C illustrate in more detail the propagation characteristics of the radiation during a typical therapy. After being delivered from the fiber optic waveguide 12, incident radiation 19 enters the irradiation device, propagates through the opening 21 in the template 22, and irradiates the portion 17 of the patient's tissue 14. While some of the radiation is absorbed, refractive index differences between the surrounding air ($n = 1$) and the tissue (typically $n = 1.5$) cause a substantial fraction 19' of the incident radiation to be reflected. For example, for both black

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and white human skin, between 4% and 7% of optical radiation from 250 and 3000 nm is reflected off the stratum corneum (i.e., the skin's upper layer). This same air/skin interface also scatters incident radiation
5 away from the skin's outer surface. Optical scattering within the skin, such as scattering from collagens in the dermis, cells in the epidermis, and other skin structures, additionally directs radiation away from the originally irradiated area.

10 Radiation propagating away from the tissue surface is collected by the reflective housing 13. Reflection off the housing redirects the re-emitted radiation 19'' back towards the tissue surface, where it irradiates the same or nearby region within the originally irradiated
15 area. Here, radiation is again partially absorbed and partially re-emitted. Although a single reflection is indicated in the figures, radiation may undergo multiple reflections in the housing before being reflected back towards the originally irradiated area. As described
20 above, to keep the irradiated area at a minimum, the reflective housing preferably has a hemispherical shape, with the irradiated region positioned at the hemisphere's center.

 In theory, this iterative process of exposing and
25 re-exposing the tissue is repeated until all the radiation propagating in the irradiation device 10 is absorbed. In practice, however, losses due primarily to the reflectivity of the reflective housing and the fact that some components in the irradiation device (e.g., the
30 fiber optic waveguide and the porthole) are non-reflective result in finite increases (i.e., gain) in the amount of delivered radiation. Typically, the gain due to the irradiation device represents between about 25% and 300% of the amount of radiation originally delivered
35 to the tissue. This gain will depend on the wavelength,

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tissue properties, device reflectance, device size, and device shape.

The actual gain in the radiation energy is determined by comparing the method according to the invention to conventional means for delivering radiation to tissues. In procedures where the irradiating device is not used, the energy E_0 of the radiation available for treatment is:

$$E_0 = E_{incident}(1-R_g) \quad (1)$$

where R_g is a coefficient indicative of the amount of radiation re-emitted from the tissue and $E_{incident}$ is the energy of the incident radiation. R_g is wavelength-dependent and has a value which is less than one: a low value of R_g means that the majority of incident radiation is absorbed by the tissue, while a high value indicates a large amount of radiation re-emission. Thus, if $R_g = .3$, then $E_0 = 0.7 E_{incident}$, meaning that 70% of the incident light is absorbed by the tissue during treatment.

The radiation energy E available for therapy when the irradiation device is employed can be expressed mathematically as:

$$E = E_0 [1 + R_g R_m + (R_g R_m)^2 + (R_g R_m)^3 + \dots] = \frac{E_0}{(1-R_g R_m)} \quad (2)$$

where R_g and E_0 are the quantities expressed above and R_m is the collective reflectance of the reflective housing. Like R_g , R_m is wavelength-dependent and has a value less than one. By comparing equations 1 and 2, the gain due to the irradiation device is expressed as:

$$gain = \frac{1}{(1-R_g R_m)} \quad (3)$$

Thus, using the device of the invention, the amount of radiation available for therapy increases as the

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collective reflectance of the reflective housing increases. Most preferably, therefore, this reflectance is made as high as possible.

Table 1, shown below, lists the increases in
5 available optical radiation as a function of the
radiation wavelength and the tissue remittance for human
skin. In all cases, R_m is 0.9 and R_g is the reflectance
value of the skin at the optical wavelength. Increases
in optical energy are calculated relative to conventional
10 therapies performed without the irradiating device.

Table 1 - Gain as a Function of Skin Remittance and Optical Wavelength

Wavelength (nm)	Application	R _s	Gain	Increase in Optical Energy
510-532	vascular treatment, tattoo and hair removal	0.3	1.37	37%
585	vascular treatment	0.3	1.37	37%
694	tattoo and hair removal, pigment treatment	0.7	2.70	170%
1064	tattoo and hair removal	0.6	2.17	117%

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From Table 1, it is evident that the gain of the radiation increases with the $R_g R_m$ product. This product can be increased by choosing an irradiating wavelength which is re-emitted strongly by the tissue or, as
5 described above, by maximizing the reflectance of the reflective housing for the irradiating wavelength.

As is evident from the Table, optical radiation near 700 nm is subjected to a gain of approximately 170% when used in combination with the irradiating device.
10 This wavelength is easily obtainable using conventional light sources (e.g., ruby, dye, diode and Ti:sapphire lasers). Thus, when used with these light sources, the irradiating device effectively triples the effective amount of radiation available for therapy. Optical
15 radiation at 1064 nm (a wavelength generated using conventional Nd:YAG lasers) is also subject to a high gain (117% increase) when used in combination with the irradiation device.

During therapy, the distribution of radiation
20 reflected from the irradiated area of tissue towards the reflective housing is typically diffuse. This is particularly true for skin, which is an isotropic medium functioning essentially as a Lambertian reflector. In this case, the intensity of re-emitted light varies as
25 $\cos(\theta)$, where θ is the angle relative to the normal vector of the skin surface. However, the amount of light collected by a hemispherical reflector varies as $\sin(\theta)$. Therefore, the contribution of a hemispherical reflector is most pronounced at $\theta = 45^\circ$, i.e., the angle where the
30 product $\sin(\theta)\cos(\theta)$ is maximized. This means that although a large fraction of radiation is gathered at angles of between about 0° and 60° from the beam path of the incident radiation, the most significant region of reflected radiation typically occurs at 45° from the
35 angle of incidence. The amount of radiation reflected at

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90° from the angle of incidence is typically negligible. Thus, it is particularly important for the reflective housing to have adequate reflective properties in the regions where the reflected radiation is concentrated
5 (i.e., around 45° from the angle of incidence and preferably the region of 0-60°). Coatings in the regions of low radiation concentrations (e.g., 90°) are less important.

Fig. 5 shows another embodiment of the
10 invention in which the reflective housing 112 of the irradiation device 100 is designed to capture and reflect the re-emitted light over the important region of approximately $\theta = 0^\circ - 60^\circ$. The reflective housing includes a hemispherically shaped upper portion 102 and a
15 conical lower portion 104 connected directly to a template 106. The template can be reduced in size or removed. In this configuration, the device, with its tapered lower portion occupying a relatively small area, is particularly effective in delivering radiation to
20 hard-to-reach places.

The irradiated area 103 of tissue 105 is positioned substantially at the center of the upper portion 102 of the reflective housing 112. Preferably, the upper portion 102 extends at an angle of at least 60°
25 from the angle of incidence of the input radiation. In this configuration, the reflective housing only contains reflective portions in regions where the contribution from re-emitted radiation intensity is high; no reflecting portion is present in the regions where the
30 reflected radiation intensity is low, i.e., from about an angle of 60° to 90° from the angle of incidence. Note that the small amount of light which is re-emitted at these angles will be reflected by the lower portion 104 of the housing towards the upper portion 102, where it

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will then be reflected back towards the original area of irradiation.

The delivery handpiece 108 and input port 110 for this device are the same as those described for the embodiment of Fig. 1. Similarly, the reflective and substrate materials in this embodiment are the same as those described above. The figure shows a reflective coating 114 deposited on the inner surface of a substrate 115. Other types of reflective housings, such as those containing grooves, may also be used with the irradiation device.

Still other embodiments of the invention are shown in Figs. 6-9. In Fig. 6, an irradiating device 120 features a reflective housing 121 including first 131 and second 122 hemispherical portions and first 127 and second 124 tapered portions. The reflective housing 121 is in contact with a template 126 and is configured to deliver re-emitted radiation to an area 128 of tissue 130. Each portion of the housing is coated with a reflective film 125 as in previous embodiments. As indicated by the arrows 119 and 123, re-emitted radiation is reflected by the coating back towards the originally irradiated region so that the amount of radiation delivered to the area 128 is increased. In this case, the first and second hemispherical portions have different diameters; the irradiated area 128 is positioned at the coincident centers of the two hemispheres. Separating the housing into first and second hemispherical portions results in a smaller amount of the re-emitted optical intensity irradiating the non-reflective region containing the fiber optic waveguide 132 and the input port 134. This is because re-emitted radiation spatially diverges after the incident beam irradiates the tissue, and thus the spatial concentration

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of radiation decreases as a function of distance from the irradiated region 128.

Fig. 7 shows another embodiment of the invention in which the irradiating device 130 includes a reflective housing 132 shaped as an ellipse. An area 136 of tissue 138 is irradiated with an incident beam delivered by the fiber optic waveguide 140. The elliptical housing is positioned with respect to a template 134 so that one of its foci is coincident with the irradiated area 136. In this way, as indicated by the arrow 133, re-emitted radiation is returned to the originally irradiated area after being reflected multiple times by the housing.

In the embodiments shown in Figs. 6 and 7, the template connected to the housing can be replaced with a plate which is transparent to the incident radiation. Like the template, the transparent plate is used to position the device on the patient's tissue and facilitate alignment of the radiation. The plate is particularly effective in aligning radiation onto tissue containing rough or curved surfaces, such as the skin.

Fig. 8 shows a cross-sectional view of an irradiating device 148 where an optical fiber 150 delivering optical radiation (indicated by the arrow 152) attaches directly to a cone-shaped, diffusely reflective housing 154. The housing 154 includes an upper opening 156 which houses the fiber, and a lower opening 158 placed in direct contact with a patient's tissue 160 (e.g., the skin). The housing 154 is preferably constructed entirely of a diffusely reflecting material, such as a white plastic, to form a highly reflecting cavity. Alternatively, the housing may be formed from a plastic, metal, glass material coated on its inner surface with a diffusely reflecting coating (e.g., a white paint or roughened metallic coating).

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During operation, radiation emitted from the fiber 150 spatially diverges (typically at an angle of about 30°, as indicated by the dashed lines 162) until it impinges the tissue 160 and is absorbed. The height of the cone thus determines the radiation spot size on the tissue, as the radiation's divergence and area increase with cone height. Typically the cone height is chosen to be about 1.5 cm. As described above, a portion of the radiation impinging the tissue is randomly re-emitted and propagates back towards the housing 154. There, the radiation is either reflected back onto the tissue or onto another portion of the housing. These processes increase the gain, or total amount of radiation which is absorbed by the tissue. In theory, the reflection process continues until all the incident light is either absorbed by the tissue or is sent back through the fiber 150. It is therefore desirable to increase the ratio between the areas of the lower 158 and upper 156 openings, as this will increase the actual amount of light redirected towards the tissue.

Fig. 9 shows another irradiating device 168 of the invention where the reflective housing consists of a optically transparent plate 170 coated on its upper surface with a dielectric coating 172. The plate 170, in turn, directly contacts the patient's tissue 160. As is well known in the art, the reflectivity of a dielectric coating depends on the angle and wavelength of the incident optical beam, and can maximized or minimized by varying the thickness and refractive index (i.e., the material composition) of the coating's dielectric layers 170a, 170b. The 'bandwidth' of the coating, i.e., the range of wavelengths or incident angles which are transmitted or reflected, depends on the refractive index and number of the layers.

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For optimum performance, the device 168 preferably includes a narrow-band, high-efficiency coating which transmits normally incident radiation (indicated by the arrow 174) and radiation which deviates from normal by
5 less than about 15°. After this radiation impinges the tissue 160, re-emitted radiation impinging the coating's bottom surface at angles greater than about 15° (indicated by the arrows 175), is reflected back towards the tissue by the coating to increase the gain. As is
10 described above, re-emitted radiation typically leaves the tissue at an angle of about 45°. This process of reflecting re-emitted radiation continues until all the radiation is either absorbed by the tissue or is transmitted through the coating.

15 Other embodiments of the irradiating device of Fig. 9 are also possible. For example, the dielectric coating can be on the bottom surface of the glass plate. The plate can also be attached directly to a faceplate or handpiece for ease of use.

20 Therapies and Other Applications

The irradiation device can be used in combination with any known radiation-based therapy to increase the gain of the radiation. Examples of such therapies include optical removal of tatoos, port-wine stains,
25 abnormal blood vessels, psoriatic skin, unwanted hair, pigmented lesions, skin cancers and other lesions treated by laser surgery, phototherapy, photochemotherapy or photodynamic therapy. Additional radiation-based therapies, particularly those used in dermatology, are
30 described in Honigsmann et al., Dermatology in General Medicines, 3rd edition, T.B. Fitzpatrick et al. (eds.) 1728-1754 (1987), the contents of which are incorporated herein by reference.

During therapy, the opening of the template or the
35 transparent plate is placed over the area to be

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irradiated. The therapy is then conducted according to standard procedures used in the optical and medical arts.

Because the effective amount of radiation which exposes the skin is increased using the irradiation
5 device, it may be necessary to decrease the amount of radiation used during therapy. Typically, the fluence of the radiation is between about 0.1 and 100 W/cm². The spatial intensity profile of the radiation can be adjusted to vary the amount at radiation-induced heat
10 delivered to the region of interest. Radiation spot diameters of between 10 microns and 1 cm are typically used.

A laser is the preferred light source for optical radiation. The laser is chosen according to the desired
15 optical wavelength. Preferred lasers include ion, dye, solid-state (e.g., Nd:YAG, Nd:YLF, Ti:Sapphire) holmium, CO₂, metal-vapor, excimer, and diode lasers. Other light sources, such as fluorescent bulbs, may also be used. The light source may be continuous-wave or pulsed.

20 The irradiation device can also be used in non-medical applications to increase the gain of the incident radiation. For example, the device can be used with a laser to cut or process materials. The device may also be used to drive photochemical reactions in certain
25 materials, such as light-sensitive films.

Still other embodiments are within the scope of the following claims.

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CLAIMS:

1. A method for irradiating a material, said method comprising:
 exposing said material with radiation, the radiation, following said exposing, being partially re-
5 emitted from the material, and
 re-exposing the material with the re-emitted radiation.
2. The method of claim 1, wherein the re-emitted radiation is reflected, scattered, or reflected and
10 scattered from the material.
3. The method of claim 1, wherein the re-emitted radiation is reflected by a reflective device to re-expose the material.
4. The method of claim 3, wherein the reflective
15 device is a reflective housing positioned proximal to the material.
5. The method of claim 4, wherein the reflective housing is comprised by an irradiating device placed proximal to the material prior to said exposing.
- 20 6. The method of claim 4, wherein the reflective housing is substantially hemispherical in shape, and the material is positioned substantially near the center of the hemisphere.
7. The method of claim 4, wherein the reflective
25 housing is substantially elliptical in shape, and the material is positioned substantially near a focus of the ellipse.

- 25 -

8. The method of claim 4, wherein the reflective housing is substantially cone-shaped and comprises a bottom opening, and the material is positioned near the bottom opening.

5 9. The method of claim 4, wherein the reflective housing is an optically transparent plate comprising a reflective coating which is substantially transparent to normally incident radiation and substantially reflects radiation incident at an angle, and the material is
10 positioned in contact with a surface of the transparent plate.

10. The method of claim 4, wherein the reflective housing comprises a reflective coating for reflecting the re-emitted radiation.

15 11. The method of claim 4, wherein said reflective housing comprises an array of grooves configured to reflect the re-emitted radiation.

12. The method of claim 1, wherein the radiation is optical radiation.

20 13. An irradiating device for delivering radiation to a material, comprising
 a reflective housing configured to receive radiation from a radiation delivery means, said housing comprising an opening or surface for placement over a
25 material and a reflective component proximal to said opening or surface, said reflective housing being shaped to receive radiation re-emitted from the material and reflect the re-emitted radiation back onto the material.

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14. The irradiating device of claim 13, wherein said reflective component is a reflective film.

15. The irradiating device of claim 14, wherein said reflective film comprises a metallic or dielectric material.

16. The irradiating device of claim 13, wherein said reflective component is an array of grooves formed in said reflective housing.

17. The irradiating device of claim 13, wherein said reflective housing is substantially hemispherical in shape and said opening is positioned at a center of the hemisphere.

18. The irradiating device of claim 13, wherein said reflective housing is substantially elliptical in shape and said opening is positioned at a foci of the ellipse.

19. The irradiating device of claim 13, wherein said reflective housing is substantially spherical in shape and said opening is disposed on a surface of the sphere.

20. The irradiating device of claim 13, wherein said reflective housing is substantially conical in shape and said opening is positioned at a base of the cone.

21. The irradiating device of claim 13, wherein said radiation delivery means is a fiber optic waveguide or an articulated arm.

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22. The irradiating device of claim 15, wherein said radiation source is a laser.

23. An irradiating device for delivering radiation to a material, comprising
5 an optically transparent plate comprising a reflective coating on a surface, said reflective coating being disposed on the plate to transmit normally incident radiation from a radiation delivery means, receive radiation re-emitted from a material, and reflect re-
10 emitted radiation incident on the coating at an angle back onto the material.

24. The irradiating device of claim 23, wherein the reflective coating comprises a dielectric material.

25. The irradiating device of claim 24, wherein
15 the reflective coating comprises multiple layers of dielectric materials.

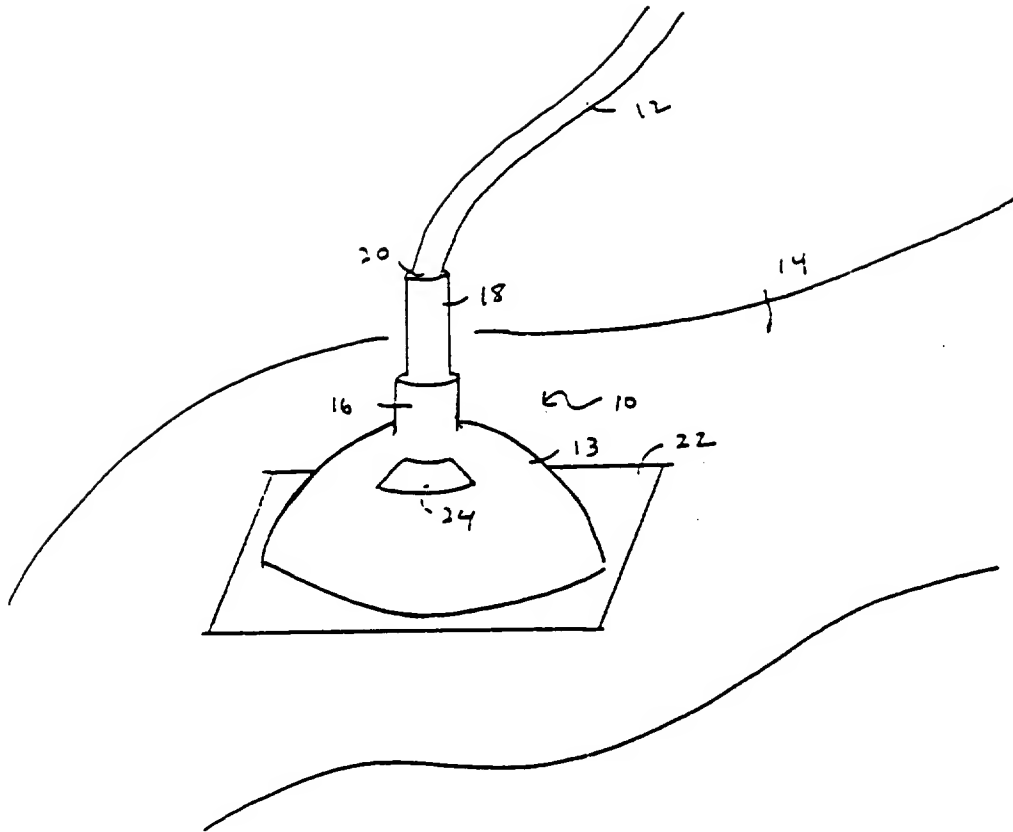


Fig. 1

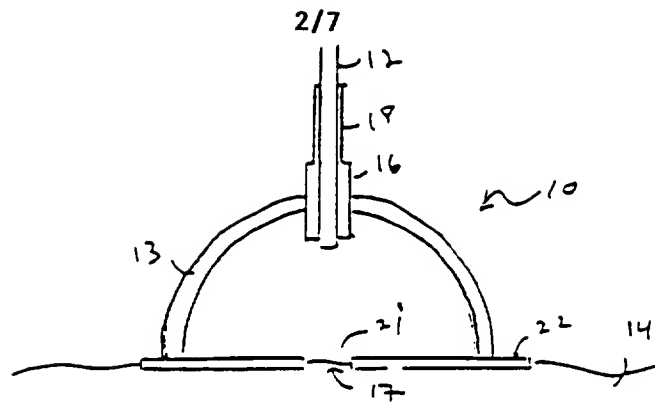


Fig. 2

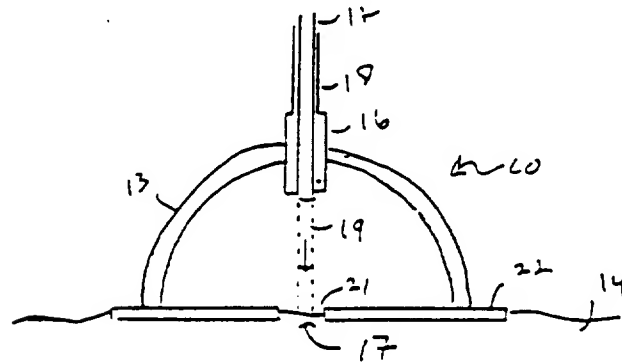


Fig. 3A

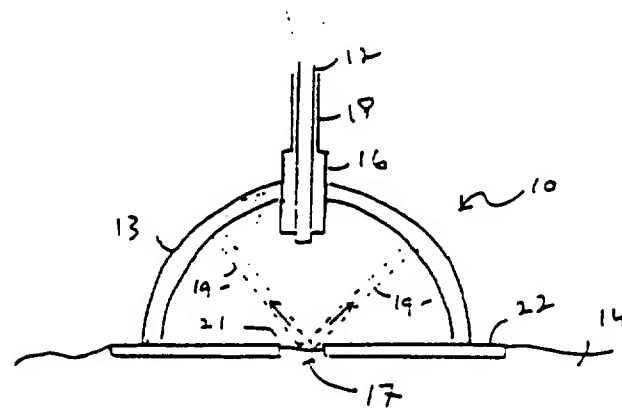


Fig. 3B

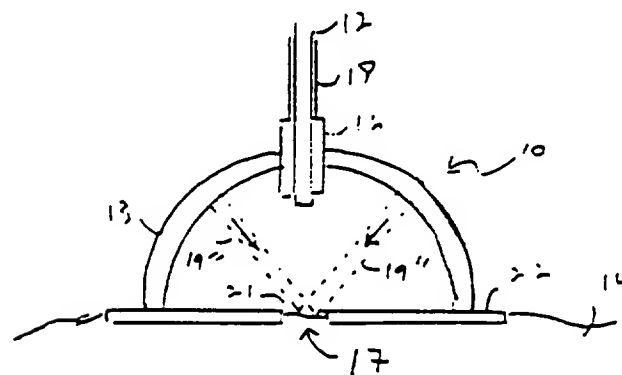


Fig. 3C

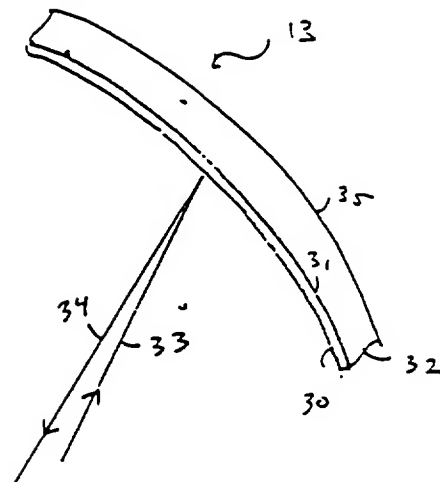


Fig. 4.4

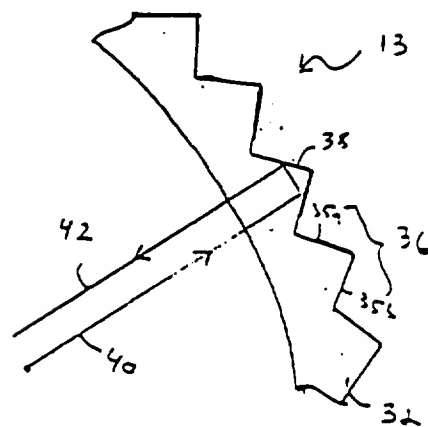


Fig. 4.13

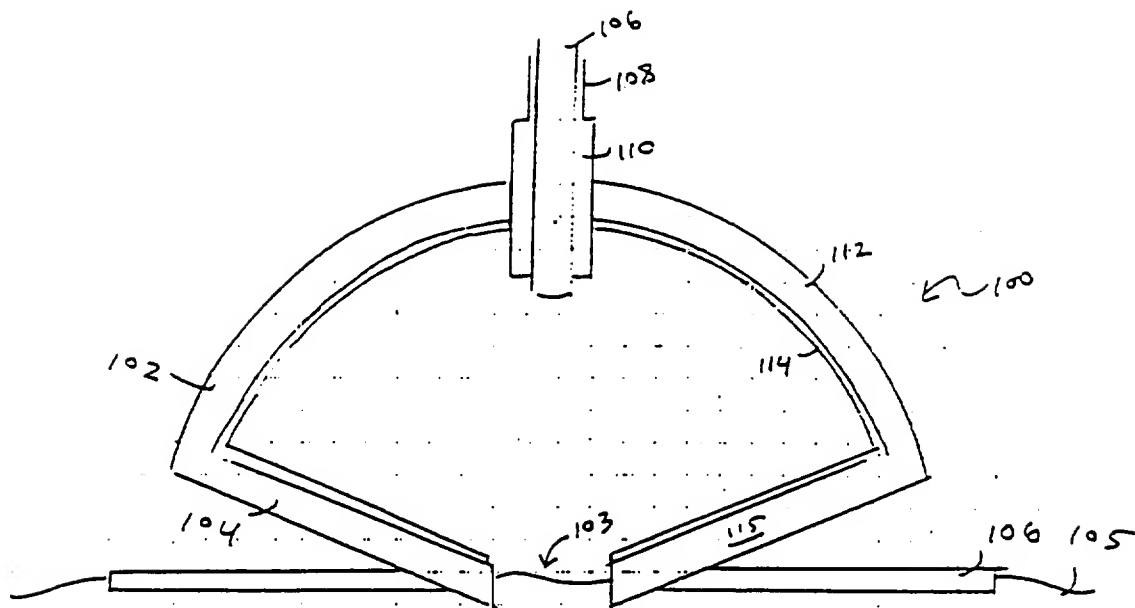


Fig. 5

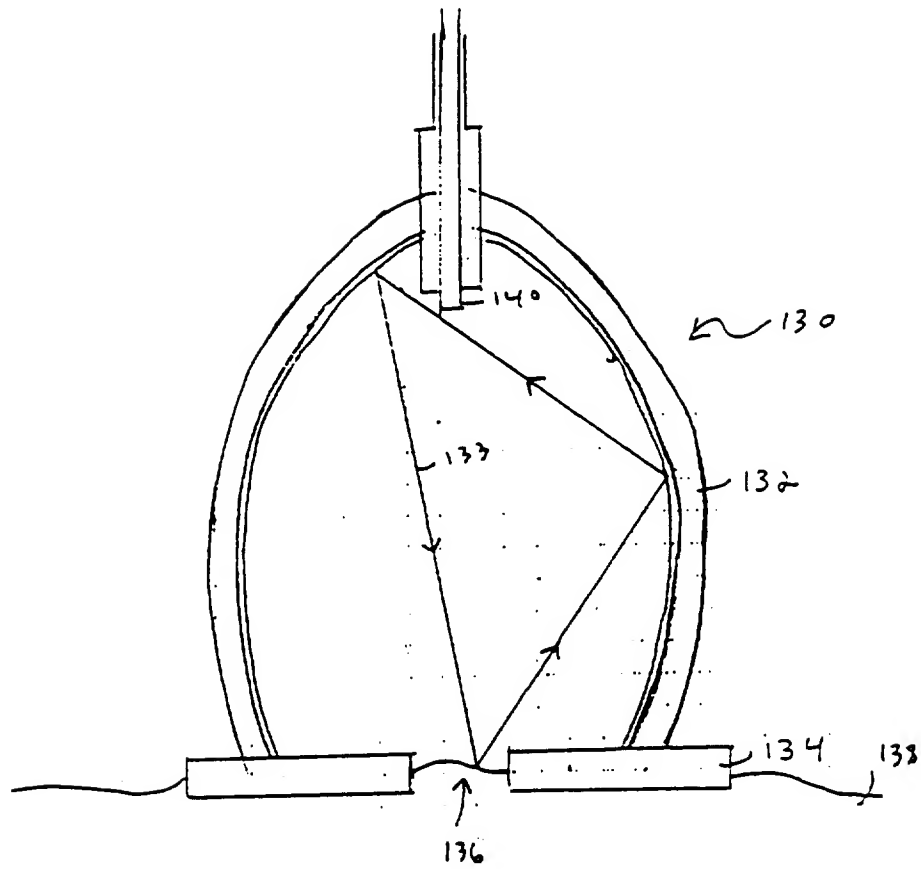


Fig. 7

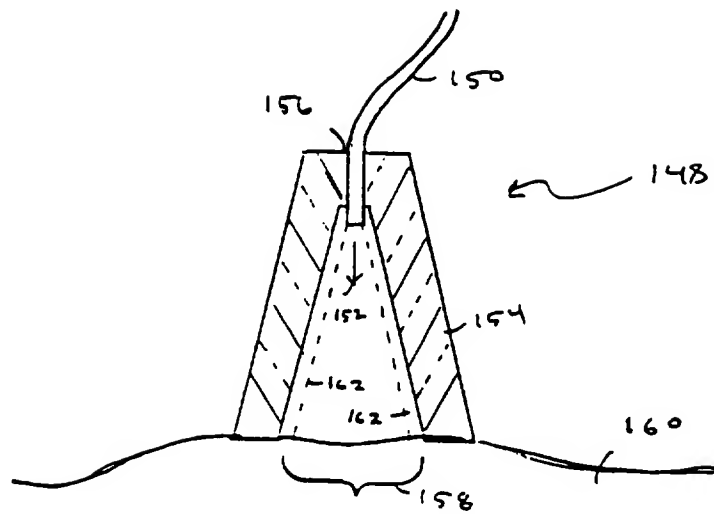


Fig. 8

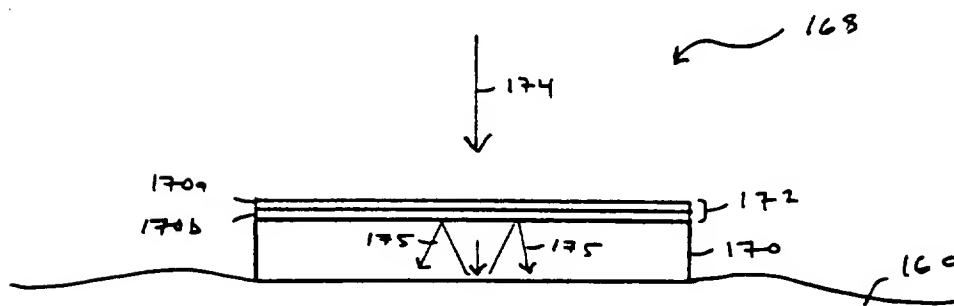


Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/16217**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) : A61B 6/00; A61N 1/00

US CL : 128/665; 606/18; 607/088

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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U.S. : 128/664, 665; 606/2, 13-18; 607/088-094

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
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NONE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,E	US 5,519,534 A (SMITH et al) 21 May 1996, entire document.	1-22
X	US 5,380,317 A (EVERETT et al.) 10 January 1995, entire document.	1-22
X	US 5,108,388 A (TROKEL) 28 April 1992, entire document.	1-22
X	US 3,527,932 A (THOMAS) 16 November 1967, entire document.	1-22
X,P	US 5,505,726 A (MESEROL) 09 April 1996, entire document.	23-25

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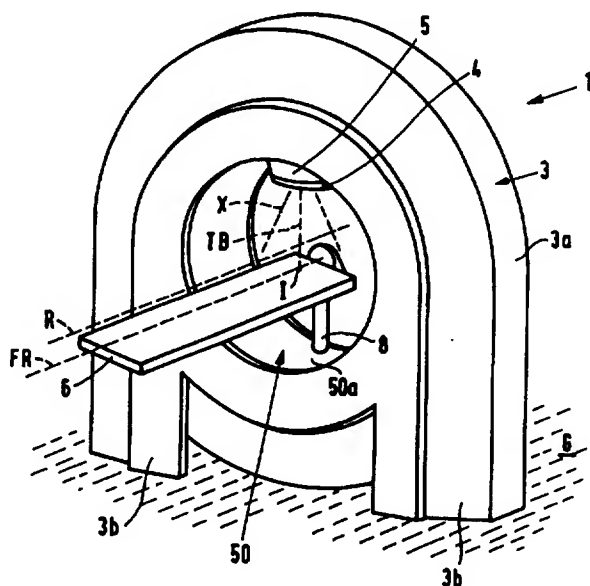
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(54) Title: RADIOTHERAPY APPARATUS FOR TREATING A PATIENT

**(57) Abstract**

A treatment source (4) such as a radiation source, is attached to the inner surface (50a) of a drum (50), which drum (50) is mounted to a support (3) so as to be rotatable with respect to the support (3) about a central axis (R) displaced from the treatment source (4). The source provides a treatment beam (X) having a treatment beam axis (TB) extending through the rotation axis (R). A patient support (6) for receiving a patient (2) to locate a target treatment area (6) on the treatment beam axis (TB) is housed at least partially within the passageway defined by the inner surface (50a). The overall size of the apparatus is thus reduced. A preferred treatment technique, to which the apparatus may be adapted, is also described.

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DESCRIPTION

RADIOTHERAPY APPARATUS FOR TREATING A PATIENT.

5 This invention relates to radiotherapy apparatus for treating a patient.

Figure 1 is a very schematic side view of one example of a known radiotherapy apparatus 100 which may, for example, be one of the range of SL series radiotherapy apparatus commercially available from Philips Medical Systems Radiotherapy, Crawley, England. As shown in Figure 1, the apparatus comprises a support 300 placed on a suitable surface G to which a gantry 310 is mounted so as to be rotatable about a rotation axis R through substantially 360 degrees or more. The gantry 310 supports an electron source 320, a linear accelerator 330 which accelerates the electrons to a suitable high energy 10 which may be in the region of 4 to 25 MeV (mega electron volts) and may be selectable. A beam deflection system 340 is provided to deflect the electrons through an angle of about or greater than 90 degrees to a treatment head 400 which includes a suitable target (not shown) onto which the electrons impinge to produce a beam X of high-energy X-rays directed along a treatment axis TB 15 which is normal to the rotation axis R. The linear accelerator 330 and deflection system 340 are arranged to bring the electron beam to a focus F which effectively forms the source of the high energy radiation beam X. A patient 2 to be treated is supported on an independent patient support 500 which is placed on the surface G and is arranged to be accurately movable in 20 directions parallel and perpendicular to the treatment beam axis TB to enable the desired treatment or target area of the patient 2 to be located at the so-called isocentre I, that is the location at which the rotation axis R and the treatment beam axis TB intersect, to ensure that the target area receives maximum radiation while the exposure to the radiation of the surrounding 25 healthy tissue is kept as low as possible.

30 Recently, several techniques have been developed for radiotherapy treatment. One such technique, tomotherapy, involves a slice-by-slice

treatment of a treatment area of a patient. Each slice is treated by a single gantry rotation, and the beams produced during the gantry rotation are constrained into a fan. Each ray of the fan beam is intensity modulated and every 5°, for example, of gantry rotation the intensity pattern is altered. A
5 tomotherapy system also houses a diagnostic computer tomography (CT) imaging unit to provide verification.

The patient is stepped through the radiation field of the gantry, to enable the slice-by-slice treatment. Although this method enables an accurate dose distribution pattern to be developed, the indexing of the patient creates field
10 matching problems, and the treatment time may be lengthy, since a complete gantry arc is required for the treatment of each slice.

An alternative approach is to use a beam which covers substantially the entire area to be treated, (a "broad beam") and the shape of the beam is modulated in two dimensions. A single gantry rotation is sufficient to enable
15 treatment of the entire area. A multi-leaf collimator, such as that produced by Philips Medical Systems-Radiotherapy and as described in EP-A-314 214 provides this two dimensional modulation. The present invention is concerned with treatments using such two dimensional shape modulated beams.

Although the apparatus of Figure 1 operates perfectly satisfactorily, it
20 occupies a relatively large area of space and moreover may be difficult to install in some buildings because of the nature of the access to the intended location for the apparatus. This may especially be the case where the apparatus is intended to replace an earlier machine such as a cobalt 60 source apparatus which requires less space.

25

It is an aim of the present invention to provide apparatus for treating a patient which may be more compact and so may be capable of being sited in smaller or more difficult access locations than previous apparatus.

According to the present invention, there is provided apparatus for
30 treating a patient by exposing a treatment area of the patient to radiation, the apparatus comprising:

a support;

a hollow body having a central aperture which defines a passageway extending through the body, the hollow body being mounted to the support so as to be rotatable about a central axis of the hollow body;

5 a radiotherapy source mounted to the hollow body so as to be rotatable with the hollow body and for projecting a radiotherapy beam within the passageway which crosses the central axis of the hollow body;

a beam limiting device for controllably partially limiting the projected area of the beam; and

10 a patient support for receiving the patient and which extends at least partly through the passageway and which is positioned such that an unlimited projection area of the beam substantially covers the treatment area of the patient.

Apparatus in accordance with the present invention enables the patient support to be at least partly accommodated within the space around which the treatment device, namely the hollow body, is to be rotated, so reducing the overall size of the apparatus in comparison to earlier apparatus.

15 The use of a hollow body to support the radiotherapy source (and other components) gives rise to a structurally stiff layout. The drum defined by the hollow body is strong and stable and will not easily deflect, improving mechanical accuracy and therefore treatment accuracy.

20 The radiotherapy source may include a linear particle accelerator disposed within the hollow body which extends in a plane which lies substantially perpendicular to a longitudinal axis of the patient support. Thus, the length of the particle accelerator does not contribute to the overall width of the treatment device, as is common in the prior art where the particle accelerator is frequently located in the gantry arm.

25 A beam deflecting means may be provided for deflecting the particle beam produced by the linear accelerator to a substantially radial direction with respect to the cylindrical passageway. Alternatively, the axis of the linear accelerator may intersect the central axis, avoiding the need for the beam deflecting means.

30 Preferably, the patient support is coupled to the hollow body and

positioned at a location opposed to the radiotherapy source.

In this way, the apparatus does not require a separate support for the patient support, thus reducing the complexity of the apparatus.

Preferably, means is provided for allowing angular movement of the patient support about the rotation axis of the hollow body and for maintaining the patient support at a substantially constant attitude relative to a fixed reference plane. The angular movement of the patient support about the rotation axis coincides with the rotation of the hollow body so that the patient support is maintained at a constant distance from the radiotherapy source. This enables the patient support to be located at a lower position (for a certain angle of the hollow body) than would otherwise be possible because less clearance is required beneath the patient support to allow the passage of the treatment device during its rotation. This should facilitate the use of standard height patient trolleys for transferring bed ridden patients to the patient support so making this transferral process easier for the medical staff involved.

In order to maintain the patient support at a substantially constant attitude, the patient support is permitted to rotate about a lengthwise axis as the patient support moves angularly about the rotation axis of the hollow body. This means that the isocentre is defined by the intersection of the rotation axis of the patient support and the axis of projection of the beam.

The coupling of the patient support to the hollow body is preferably arranged to allow translational movement of the patient support with respect to the body in one or more directions parallel to or perpendicular to an axis of projection of the beam. This enables accurate positioning of the target treatment area at the isocentre.

The apparatus may further comprise an imaging radiation source which is also mounted to the hollow body, and a radiation detection device mounted to the hollow body at a location which is opposite to the imaging radiation source. In this way, the apparatus may carry out the image scanning procedure as well as the treatment procedure, and this may preferably be carried out in a single continuous operation. Preferably, the radiotherapy source is supplied by a megaelectron volt source whereas the imaging source

is supplied by a kiloelectron volt source. The apparatus may also include a beam stop positioned opposite the treatment source, and/or a MeV imaging head which can provide verification of the treatment administered by the MeV treatment head during treatment.

5 The hollow body may comprise an inner portion within which is defined the passageway, and an outer portion, the inner and outer portions being rotatable with respect to each other, the radiotherapy source being mounted on the outer portion of the hollow body, and the beam limiting device being mounted on the inner portion of the hollow body.

10 In this way, the beam limiting device can be rotated from a treatment position during which it is aligned with the radiotherapy source. This will facilitate servicing of radiotherapy source.

 Preferably, an imaging source is mounted on the outer portion of the hollow body at a position displaced from the radiotherapy source, the relative
15 rotation between the two hollow body portions enabling the radiotherapy source or the imaging source to be aligned with the beam limiting device. In this way, imaging can be carried through the same beam limiting device as will be used for the treatment, so that accurate simulation of the treatment can be carried out.

20 The imaging source may comprise a light source, if insufficient funds are available for electronic imaging, but preferably the imaging source comprises an X-ray source, and the apparatus further comprises an X-ray image detecting device mounted on the inner portion of the hollow body, opposite to the beam limiting device.

25 The X-ray image detecting device may be slidably received by the inner portion of the hollow body so as to be slidable between a first position opposite to the beam limiting device and a second position displaced from the first position, the angle of displacement between the two positions corresponding to the angle of displacement between the imaging source and the radiotherapy
30 source. In this way, the imaging detecting device may be positioned opposite the image source either with or without the beam limiting device interposed between the two. Thus, localisation of the treatment area can be carried out

without the restriction of the beam limiting device, but beam limiting device may be used for image detection during simulation, and for verification during the treatment procedure.

As explained above, the apparatus of the invention is for treatment using
5 a so-called "broad beam". One proposed radiotherapy treatment technique which uses two dimensional modulation of the beam shape involves delivering beams from a limited number, for example 5 to 7, of directions around the arc swept by the gantry. At each of these positions, the two dimensional shape of the delivered beam is modulated, for example using a multi-leaf collimator .
10 Furthermore, the intensity of each elemental ray within the beam may also be modulated. This intensity modulation may be performed by altering a duty cycle of the leaves of the multi-leaf collimator. This technique uses a reduced number of treatment positions, and it is therefore necessary to optimise the dose distribution at each of these positions. As a result, it may be desirable to
15 alter the angle of the patient support between treatment beams, so that each beam delivers an optimum treatment. Thus, oblique beam entry angles may be employed. It may alternatively be desirable to carry out the entire treatment with an oblique angle of the patient support. The apparatus according to the invention may be adapted to allow pivoting of the patient support with respect
20 to the hollow body to permit such oblique entry angles. However, by virtue of the enclosed nature of the treatment volume within the passageway of the hollow body, the apparatus according to the invention is not ideally suited to patient manipulation during the treatment process.

The apparatus according to the invention is particularly suited to a
25 treatment technique which is currently being developed by the applicant, in which a beam is produced at a large number of positions around a gantry arc of rotation (for example every 5°) with a fixed intensity beam being applied for the entire gantry arc. A number of gantry rotations are required to build up a complex intensity pattern.

30 Thus, the apparatus preferably comprises controlling means for providing a first beam of a first fixed intensity and controlling the beam limiting device to selectively limit the projection area of the beam at a variety of positions of the

hollow body during a first rotation of the hollow body, and for providing a second beam of a second fixed intensity and controlling the beam limiting device to selectively limit the projection area of the second beam at a plurality of positions of the hollow body during a second rotation of the hollow body.

5 The controlling means may therefore continuously alter the shape of the fixed intensity beam during a rotation of the gantry (namely the hollow body) and in this way the change in patient set up between beams is not appropriate. The controlling means preferably comprises a computer system, as is known for controlling a multi leaf collimator.

10 The number of hollow body rotations that will be required will depend on the complexity of the intensity pattern which is desired to be implemented and this will depend partly upon the number of intensity peaks which are desired to be delivered.

15 The continuous nature of this treatment technique eliminates the need to provide for oblique entry angles so that access to the patient is not required during the treatment procedure. As a result, the apparatus of the invention may be particularly suited to the provision of such a treatment technique.

20 The invention also provides a method of operating the apparatus according to the invention so as to enable the above described treatment technique to be implemented.

As used herein, the term "projection area" should be interpreted as meaning the shape of the beam, in a plane perpendicular to the direction of projection of the beam, which has been transmitted through the beam limiting device.

25 The term "beam" should be understood to include not only the direction of continuous beams of particles or radiation, but also the direction of pulsed or discontinuous sequences of particles or radiation at a target area.

Finally, the term "attitude" means the angular orientation of the patient support about its lengthwise axis relative to the fixed reference plane.

30

Embodiments of the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows a very schematic side view of a conventional radiotherapy apparatus;

Figure 2 shows a very schematic perspective view of one example of radiotherapy apparatus in accordance with the invention;

5 Figure 3 shows a very schematic perspective view of the internal components of the apparatus shown in Figure 2.

Figure 4 shows a very schematic cut-away and part-sectional side view of part of the apparatus shown in Figure 2;

10 Figure 5 shows a diagrammatic cut-away schematic side view of a portion of the apparatus shown in Figure 2 for illustrating one possible way of controlling angular movement of the patient support;

Figure 6 shows a diagrammatic cut-away schematic side view of a portion of the apparatus shown in Figure 2 for illustrating another possible way of controlling angular movement of the patient support; and

15 Figures 7 to 9 are diagrammatic sketches for illustrating the operation of the apparatus shown in Figure 2.

Figure 10 shows a second example of radiotherapy apparatus in accordance with the invention, during an imaging mode of operation;

20 Figure 11 shows the radiotherapy apparatus of Figure 10, during a simulation mode of operation;

Figure 12 shows the radiotherapy apparatus of Figure 10, during a treatment mode of operation; and

Figure 13 is a diagram explaining the preferred treatment technique.

25

It should of course be understood that the drawings are not to scale and that like reference numerals are used throughout the text to refer to like parts.

30 Referring now to Figures 2 to 8 of the drawings, there is illustrated apparatus 1 for treating a patient 2, which apparatus comprises a support 3, which notably supports a hollow body in the form of a drum 50 having a cylindrical inner surface 50a defining a passageway. Of course, the

passageway need not have a cylindrical inner surface, but can have any shape in which the patient support can be positioned. A treatment source 4 is mounted to the cylindrical surface 50a so that the treatment source 4 is rotatable about a rotation axis R displaced from the treatment source 4 and provides a treatment beam X having a treatment beam axis TB extending from the treatment device 4 through the rotation axis R. A patient support 6 for receiving a patient 2 is positioned so as to locate a target treatment area of the patient 2 on the treatment beam axis TB.

Apparatus 1 in accordance with the present invention enables the patient support 6 to be at least partly accommodated within the space around which the treatment device 4 is to be rotated, so reducing the overall size of the apparatus in comparison to earlier apparatus. The patient support 6 may be coupled to the inner cylindrical surface 50a of the drum 50, or to the support 3. In either case, the apparatus does not require a separate support for the patient support 6.

If, as is preferred, the patient support 6 is coupled to the inner surface 50a of the hollow body, the coupling is such as to maintain the patient support 6 at a substantially constant attitude with respect to a fixed reference plane. This coupling allows the patient support to be displaced from the rotation axis, and as a result, the overall diameter of the apparatus may be reduced, and this may, in the case of a linear accelerator (LINAC) radiotherapy apparatus, allow a straight through system to be used without increasing the size of the apparatus. A straight through system removes the need for a beam deflection system.

Figures 2 and 3 are diagrammatic perspective views of one example of apparatus 1 in accordance with the invention. Figure 4 shows a corresponding side view in which the support 3 and drum 50 have been shown cut-away to enable a clearer understanding of one possible construction.

In this example, the support 3 comprises a generally hollow cylindrical housing 3a having integral supporting members 3b which support the housing 3a on a surface, normally a suitably reinforced, generally ground or basement,

floor of a building. In this example, a surface also forms the fixed reference plane G. The drum 50 is mounted using a conventional bearing arrangement (not shown) within the housing 3a and a drive arrangement (not shown) is provided for allowing the drum 50 to be rotated about its axis. The bearing and drive arrangements may be similar to those used in conventional radiotherapy apparatus, such as the SL series manufactured by Philips Medical Systems-Radiotherapy at Crawley, England. The drive arrangement may be a friction drive arrangement or a geared arrangement as will be briefly described below with reference to Figures 5 and 6.

The treatment source 4 is in this example a radiotherapy source comprising a high energy electron source 4a, associated LINAC 4b and treatment head 4 for producing a high energy X-ray beam X in a manner similar to that described above in relation to Figure 1. As shown schematically in Figure 3, the longitudinal axis of the LINAC 4b lies in a plane which is perpendicular to the longitudinal axis of the patient support 6. As a result, the overall width of the apparatus is kept to a minimum, and there is no need to provide extending gantry arms which have conventionally housed the required LINAC. As seen in Figure 3, the LINAC 4b is positioned within the hollow body and lies in a plane substantially perpendicular to the length of the patient support. In this way, the LINAC does not contribute to the overall width of the apparatus. The LINAC also extends in a tangential direction, so that the diameter of the hollow body can be kept to a minimum. A beam deflection unit 4c is provided to direct the beam into a radially inward path towards the treatment head 4.

The treatment source 4 includes a beam limiting device, in the form of a multi-leaf collimator for example as described in EP-A-314214. The multi-leaf collimator is capable of controlling the dose delivered to each elemental ray of the beam by controlling movement of the leaves. In this way, it is possible to create a two dimensional intensity pattern. The elemental rays typically have 1cm x 1cm dimensions, the entire beam covering an area of 20cm x 20cm. This beam area is generally sufficiently large to cover the treatment area of the patient.

Alternatively, the construction of the apparatus 1 may allow for the use of a shorter LINAC which can be provide straight through feed, removing the need for a beam deflection system 4c. In this case, the LINAC 4b is aligned with the treatment source 4.

5 The treatment source 4 is mounted using suitable conventional radiotherapy mounting techniques to the inner surface 50a of the drum 50 so that the housing 5 of the treatment source 4 is fixed in relation to the inner surface 50a of the drum 50. The treatment source 4 itself may of course be rotatably mounted within its housing 5 in known manner. The mounting is
10 arranged to enable a treatment beam X to be directed normally of the rotation axis R so that the treatment beam axis TB intersects the rotation axis R.

 The patient support 6 may be fixed with respect to the housing 3a, although with flexibility to position the support so that the treatment area of the patient coincides with the isocentre I. Thus, no alignment of the patient support
15 is required at installation of the apparatus.

 However, the patient support 6 is preferably mounted to the inner surface 50a of the drum 50 and is arranged so as to be diametrically opposed to the treatment source 4. As illustrated very schematically in Figure 4, the patient support 6 is mounted to the inner surface of the drum 50 by means of
20 a support member 8 which has one end 8a coupled to the inner surface 50a of the drum 50 and the other end coupled to a connection member 60 of the patient support 6 so as to enable the patient support 6 to rotate about a further rotation axis RF which is parallel to the rotation axis R. Rotation about the axis RF is required so that the patient support can maintain a constant attitude.
25 Generally, although not evident from Figure 2 or Figure 3, the support member 8 will allow for translational movement of the patient support parallel and perpendicular to the treatment beam axis TB. The further rotation axis RF defines with the treatment beam axis TB the isocentre I at which the target area of the patient is to be located. The patient support 6 could be arranged to
30 rotate about an axis coincident with the rotation axis R of the drum but, as will be evident from the discussion below with reference to Figures 6 to 8, the displacement of the further axis RF from the rotation axis R in a direction away

from the treatment source 4 enables a more compact arrangement because a smaller clearance is required between the patient support 6 and the inner surface 50a of the drum 50 when the further axis RF is so displaced from the rotation axis.

5 If the further axis RF is made to coincide with the rotation axis R, then the patient support 6 will remain stationary in the centre of the cylindrical opening 50a. Such an arrangement is mechanically equivalent to an arrangement in which the patient support 6 is fixed to the housing 3a. This equivalence may be obtained by adjusting the position of the patient support
10 6, in the manner described in the following.

When the patient support is mounted to the drum 50 opposite to the treatment source 4, it provides a counter balancing weight to that of the treatment source, for all positions of the drum. This produces a stable structure. The location of the isocentre within the cylindrical passageway of
15 the drum 50 also gives rise to a stable arrangement.

In addition, it may be desirable to position a beam stop opposite the treatment source. In conventional systems, although a beam stop may be desirable, it usually compromises the mechanical stability of the apparatus, since it requires a further gantry arm positioned opposite the treatment source
20 gantry arm. In the apparatus according to the invention, the design of a beam stop may in fact result in more effective balancing of the apparatus. Alternatively or additionally, a MeV imaging source may be provided opposite to the treatment head, so as to provide treatment verification. This may also improve the balance of the apparatus.

25 The drum 50, support member 8 and associated couplings result in the patient support 6 being coupled to the treatment source 4 and may allow the position of the patient support 6 to be adjusted along the direction of the treatment beam axis TB and along the direction of the further rotation axis RF (and possibly also along a direction perpendicular to the treatment beam axis
30 TB and the further rotation axis RF) to facilitate accurate positioning of the target area 2a at the isocentre I.

As indicated in Figures 2 and 4, the support member 8 is provided at

one end (as shown the "head" end) 6a of the patient support 6. Although, a single support member 8 should generally be sufficient, if considered desirable, as illustrated very schematically in Figure 4, a further support member 8' and associated connection member 60' may be provided at the other end (the "foot" end as shown) 6b of the patient support 6. Such a supplementary support member 8' would of course be constructed so as to cooperate with the support member 8 and be arranged to follow the movements of the support member 8. The support member or members may, of course, be positioned at any convenient location and could in some circumstances be movable relative to the inner surface 50a of the drum 50.

As the patient support 6 is coupled to the drum 50, it moves angularly about the rotation axis R. Rotation of the support 6 about the axis RF is designed to ensure that a constant attitude of the patient support 6 is maintained, as previously mentioned.

Any suitable arrangement may be used to enable the patient support 6 to be maintained at this substantially constant attitude, in this example parallel, with respect to the fixed reference plane G. In this example, the fixed reference plane G happens to coincide with the support surface upon which the apparatus is mounted.

One way of enabling the patient support 6 to be maintained at a substantially constant attitude is the use of a suitable gearing arrangement to control the angular movement of the patient support 6 in accordance with the rotation of the drum 50. Figure 5 illustrates one possible gearing arrangement by way of a very schematic view of the appropriate part of the apparatus with the support member 8, the drum 50 and the housing 3a shown cut-away to enable the internal components to be seen.

In the example illustrated in Figure 5, a drive wheel 11 is fixed against rotation to the output or drive shaft 12 of a motor 13 mounted to an interior wall or support 30 of the housing 3a. The drive wheel 11 meshes with a gear wheel or other suitable toothed surface 14 which circumscribes the interior 50a' of the inner surface 50a of the drum 50 so that operation of the motor 13 causes the drum 50 to rotate about the rotation axis R.

A first shaft 15 extends through the inner surface 50a of the drum 50 and is mounted by way of a suitable bearing or journal (not shown) so as to be capable of rotation about its longitudinal axis 15a. A lower end 15b of the first shaft 15 carries a gear wheel 16 which is fixed against rotation with respect to the first shaft 15. The gear wheel 16 meshes with a toothed surface or wheel 17 fixed to and circumscribing an interior cylindrical surface 31 of the housing 3a which is coaxial with the drum 50.

The other end 15c of the first shaft 15 carries a first bevel gear 18 which meshes with a second bevel gear 19 provided on one end 20a of a second shaft 20. The other end 20c of the second shaft 20 carries a third bevel gear 21 which meshes with a fourth bevel gear 22 carried by one end 23a of a third shaft 23. The other end 23b of the third shaft 23 carries a fifth bevel gear 24 which meshes with a sixth bevel gear 25 carried by one end 26a of a fourth shaft 26. The shaft 26 extends through and is rotatably journaled to the housing 80 of the support member 8. The other end 26b of the shaft 26 is fixed to the connection member 60 so that the axis 26c of the shaft 26 coincides with the further rotation axis RF.

Translational movement of the patient support 6 parallel or perpendicular to the treatment beam axis TB to allow the desired target area 2a to be precisely located at the isocentre I may be achieved by making the first and second shafts 15 and 20 telescopic as illustrated very schematically in Figure 4 so that each shaft consists of two or more shaft members 15' and 15" and 20' and 20" and using an appropriate drive system such as the pneumatic or hydraulic arrangements commonly used in conventional LINAC radiotherapy apparatus or a worm gear train drive arrangement to effect relative movement of the telescoping shaft members.

In such a case, the associated shaft members 15' and 15" and 20' and 20" would of course be secured against relative rotation about their longitudinal axis by any suitable means. Thus, for example, the shaft members 15' and 15" and 20' and 20" may be of non-circular cross-section so as to allow only relative longitudinal movement and not relative radial movement or may be provided with corresponding longitudinally extending tongues and grooves

which engage to prevent relative radial motion but allow relative longitudinal movement of the respective shaft members 15' and 15" and 20' and 20".

Such an arrangement allows for the height or position of the patient support 6 along the treatment beam axis TB to be adjusted and also allows for movement of the patient support 6 along the rotation axis R to position the correct target area 2a within the path of the beam X and at the isocentre I.

To adjust the further rotation axis and thus the isocentre I relative to the patient support 6 to compensate for different sizes or bulks of patients 2, the further rotation axis RF may be made movable with respect to the surface 61 of the patient support 6 by, for example, forming the connection member 60 as two or more telescopic members 60a and 60b, as illustrated schematically in Figure 4, which, in a manner similar to the shaft members 15' and 15" and 20' and 20", allow relative longitudinal but not relative rotational movement, and by using an appropriate drive arrangement as discussed above.

The housing 80 of the support member 8 is formed of correspondingly telescoped housing parts 80a, 80b and 80c to accommodate telescopic movement of the shaft members 15' and 15" and 20' and 20". As will be appreciated, the shaft 23 should be of sufficient length to provide clearance for rotation of the patient support 6.

With such an arrangement, operation of the drive arrangements for the telescopic shafts 15' and 15" and 20' and 20" (and 60a and 60b, if present) allows the desired target area 2a of the patient 2 to be located precisely at the isocentre I. Operation of the motor 13 causes the drum 50 to rotate about the rotation axis R. This rotation results, by way of the combination of gear wheels 16 and 17, in the rotation about its longitudinal axis 15a of the first shaft 15 so causing, by virtue of the meshing of the bevel gears 18 and 19, the second shaft 20 to rotate about its axis 20b which, by virtue of the meshing of the bevel gears 21 and 22, causes the third shaft 23 to rotate about its axis 23c which in turn, by virtue of the meshing of the bevel gears 24 and 25, causes the fourth shaft 26 to rotate about its axis 26c, so causing the patient support 6 to rotate about the further rotation axis RF and thus to effect angular movement about the rotation axis R. With the appropriate gear ratios, which may

generally be 1:1, the gearing arrangement causes the patient support 6 to maintain a constant, in this case a horizontal, attitude with respect to the fixed reference plane G. Such an arrangement allows control over the rotation of the patient support 6 and allows, if desired, the constant attitude to be other
5 than horizontal.

Where, as mentioned above in relation to Figure 2, a supplementary support member 8' is provided, the construction and coupling of that support member 8' may be similar to those of the main support member 8 and operation of the telescoping arrangements will of course be controlled so as to
10 maintain the constant attitude of the patient support 6. Of course, the rotational coupling between the supplementary support member 8' and the supplementary connection member 60' may be simply a pivot pin 9 (as shown in phantom lines in Figure 4) which allows the coupling to follow the driven rotation at the other end 6a of the patient support 6.

Although not shown, another possible gearing arrangement would be to
15 mount the patient support 6 within a large gear wheel having its axis of rotation coincident with the further rotation axis RF and using an appropriate gear train drive gear to rotate the gear wheel. The gear wheel need not necessarily form a complete circle but need only be segment of a circle of sufficient extent to
20 allow the required degree of rotation of the patient support 6 about the further rotation axis RF. Such a gear wheel could be displaced from the line of sight of the treatment source 4. In such a case, the patient support 6 may be mounted to the gear wheel so as to be slidable in a direction parallel to the axis of rotation RF and the gear wheel itself may be arranged, in a manner similar
25 to that described above, so as to be movable in a direction parallel to the treatment beam axis TB to allow accurate positioning of the target area 2a at the isocentre I.

Figure 6 shows a view similar to Figure 5 of an alternative arrangement for enabling the patient support 6 to be maintained at a substantially constant
30 attitude. This arrangement differs from that described above in relation to Figure 4 in that the gear trains are dispensed with and rotation of the patient support 6 is controlled by a separate motor 27 mounted to a shaft 28. In order

to allow translational movement of the patient support 6, the shaft 28, which is generally U-shaped, forms a first telescopic arrangement with a further generally U-shaped shaft 29 which itself forms a second telescopic arrangement with another shaft 30 having its other end mounted to the housing 80 or the surface 50a. The telescopic arrangements are controlled as discussed above with reference to Figure 4 and operation of the motor 21 is controlled electronically in accordance with the operation of the motor 13 by appropriate controls 31 coupled between the motors 13 and 27.

As can be seen from the Figures, the arrangement of Figure 6 operates in a similar manner to that shown in Figure 5 except that the function of the gear train is performed by the motor 27 which is a servo-following motor driven in response to the motor 13. This avoids the need for gear trains which are subject to wear and also, potentially, backlash and facilitates the use of computer control of the apparatus 1 which should enable greater precision.

As another possibility, the patient support 6 may be made sufficiently heavy to cause it to rotate about the further axis RF to maintain a horizontal attitude simply under the influence of gravity. In such a case, the motor drive shown in Figure 5 may simply be omitted so that the shaft 28 provides a pivot pin to which the connection member is journaled to allow the patient support 6 to rotate about the further axis RF under the influence of gravity. Suitable damping may be provided by, for example, friction, hydraulic or pneumatic means. Such an arrangement is relatively cheap and simple to manufacture.

Figures 7 to 9 are schematic diagrams for illustrating the operation of the apparatus 1 described above as the treatment source 4 rotates.

Figure 7 shows the apparatus 1 in a starting condition with the treatment source 4 above the patient support 6. In this example, the radial distance A from the inner surface of the drum to the isocentre I is taken to be 80 cm (centimetres) while the isocentric distance I_d from the isocentre I to the X-ray target indicated as F in Figures 6 to 8 is 100 cm and the height of the LINAC (or the beam deflection system where a straight through LINAC is not used) is 40 cm in total with 20 cm of that total being outside the drum 50 in the spacing provided by the housing (not shown). The clearance of the drum 50 above the

fixed reference plane G is 20 cm.

Figure 8 illustrates the situation when the treatment source 4 has rotated 90 degrees clockwise from the position shown in Figure 7 while Figure 9 illustrates the situation when the treatment source 4 has rotated 90 degrees clockwise from the position shown in Figure 8. As can be seen from these Figures, the pivotal coupling between the support member 8 and the patient support 6 and any associated drive arrangement cause the patient support 6 to maintain a constant attitude despite the rotation of the drum 50. Thus, in the example shown, the patient support 6 remains horizontal and is thus substantially parallel to the support surface which also forms the fixed reference plane G in this case with, of course, the patient 2 uppermost.

Also, as can clearly be seen from Figures 7 to 9, the fact that the isocentre I does not need to be coincident with the axis of rotation R means that the patient support 6 and the isocentre I are further from the support surface G in the position shown in Figure 8 than in the position shown on Figure 6 so facilitating passage of the treatment source 4 beneath the patient support 6. Thus, this apparatus requires less clearance between the drum 50 and the supporting floor G than is required between the floor and gantry of conventional radiotherapy apparatus. This allows the patient support 6 to be located at a lower position than would otherwise be possible and thus should facilitate the use of standard height patient trolleys for transferring bedridden patients to the patient support 6 so making this transferral process easier for the medical staff involved.

Systems have been provided in which a channel is set into the floor so that the rotating gantry arm can pass beneath floor level. This allows the apparatus to be positioned lower down, so facilitating access to the patient and the use of patient trolleys. However, when manipulation of the patient is desired, the channel may provide a hazard to the operator. As discussed above, the apparatus of the invention, when incorporating a patient support which is displaced from the rotation axis, allows the patient support to be positioned lower down, for some angles of rotation of the hollow body. In addition, it may be possible to use the reduction in the diameter of the drum to

enable a straight through LINAC to be used. This may increase the diameter of the drum, and it may therefore still be desirable to set the apparatus in a channel in the floor. As a result of the enclosed nature of the apparatus of the invention, the channel in the floor will not be exposed to the operating staff, since there are no gantry arms. Thus, any hazards or inconvenience normally associated with such an arrangement are avoided.

The space between the drum 50 and the housing 3a may be used to accommodate control equipment of the apparatus so allowing for a very compact arrangement.

As described above, the patient support 6 may remain stationary within the passageway defined by the cylindrical wall 50a. This may be achieved either by fixing the support 6 to the housing 3a, or, when the support is fixed to the inner surface 50a of the drum 50 as described above, by suitable positioning of the patient support 6. This may be desired if an imaging arrangement is also provided on the inner surface 50a of the drum 50.

Such an arrangement is known in the art and comprises a KeV imaging source 50 which in the apparatus of the invention is located at one point around the drum, and an image sensor SE located diametrically opposite the imaging source.

The imaging source SO and sensor SE could be provided at 90° to the treatment source 4, again balancing the rotating drum 50, as shown in phantom lines in Figure 7. In such a case, it is essential for the patient support to remain stationary at the rotation axis R during the image sensing procedure. As described above, this may be achieved by appropriate positioning of the patient support 6.

A system may be desired in which simultaneous imaging and treatment are provided, preferably with verification by having a MeV imager opposite the treatment head. In this case, it is preferred that the patient is permanently located on the rotation axis.

Generally, the attitude of the patient support should remain constant with respect to a plane G extending at a given angle, generally perpendicularly, to the treatment beam axis TB and thus the fixed reference plane should really

be considered to be fixed with reference to the treatment beam axis TB. However, as indicated above, in most cases the fixed reference plane will be the horizontal and will be generally parallel to the plane of the support surface on which the apparatus is stood and so that support surface can be considered to be the fixed reference plane.

Although in the above-described examples, the treatment source 4 comprises a high energy X-ray radiation source for directing a beam X of radiation at the target area 2a of the patient 2, the present invention may be applied to apparatus using gamma radiation or particle radiation. Also, of course, the treatment beam need not necessarily be continuous but could be pulsed or discontinuous.

A second example of radiotherapy system according to the invention is shown in Figures 10 to 12. The same reference numerals are used for components in common with the first embodiment. The hollow body 50 and mounted components only are shown, but the hollow body 50 is to be rotatably mounted to a support as in the first embodiment, and a patient support 6 is also provided. The apparatus of the second embodiment is particularly for providing tumour localisation as well as treatment, and therefore, as discussed above, the patient support 6 is preferably stationary on the rotation axis R of the hollow body 50. This is most easily achieved by fixing the patient support 6 to the support of the hollow body. Again, the patient support 6 may have some freedom to rotate about a vertical axis, to allow oblique treatment angles. Of course, it is possible to provide coupling of the patient support to the hollow body as described in relation to the previous example, if desired.

Once more, the hollow body 50 is in the form of a drum having an inner surface 50a defining a passageway. The passageway may have a cylindrical inner surface, but can have any shape in which the patient support 6 can be positioned. The treatment source 4 is mounted to the drum so that the treatment source 4 is rotatable about a rotation axis R displaced from the treatment source 4 and provides a treatment beam X having a treatment beam axis TB extending from the treatment device 4 through the rotation axis R. The

patient support 6 for receiving a patient 2 is positioned so as to locate a target treatment area of the patient 2 on the treatment beam axis TB.

The second embodiment provides a modular arrangement of components of the radiotherapy system, so that the system can be tailored to the expertise or finances of a particular user. For example, the finances
5 available to some countries may prohibit the use of a sophisticated Computer Tomography scanning system, or the use of a treatment device using expensive multi-leaf collimators and the associated control systems.

Radiotherapy systems do exist which provide less advanced treatment
10 programs than those possible using advanced computer tomography generated images and multileaf collimator generated beam shapes. However, even these systems include a separate localising apparatus and treatment apparatus. Thus, a localising apparatus is provided for localising a treatment area of a patient, namely the area to be irradiated, by using a KeV radiation source and
15 imaging device. This may involve providing an imaging beam at, for example, two or four positions around the patient. This then enables the desired treatment beam shape to be determined for those angles. The localising apparatus also enables simulation to be carried out, which involves adjusting a collimator to provide a beam limiting function which generates the desired
20 treatment beam shape. In order to verify the beam shape produced by the collimator, a light source may be provided so that visible adjustment of the collimator can take place.

The collimator used is generally a device which enables only a rectangular beam limiting function to be achieved. The use of a multileaf
25 collimator for the treatment, which is a more expensive apparatus and necessitates expensive control algorithms and more experienced operators, may not be financially possible.

In a more advanced system where the treatment is to involve the use of a multileaf collimator, the collimator used for simulation with the KeV imaging
30 source will not be of the same type as that used for the treatment, and a multileaf collimator is generally not used for treatment simulation at all. Furthermore, a MeV treatment collimator requires leaves of significant depth to

absorb the high energy radiation which is to be blocked, which leads to a very heavy treatment collimator with accordingly powerful control systems. Since this high level of radiation absorption is not required by the collimator used for simulation of the collimator settings, a different, less expensive, beam limiting device is used for simulation.

Having determined the collimator positions for the different treatment beams, a separate treatment apparatus, having a MeV radiotherapy source, is used for the radiotherapy treatment.

The apparatus of the first embodiment of the invention enables the imaging arrangement to be provided in the same apparatus as the treatment head, so providing the possibility of sequential scanning and treatment, without repositioning the patient. The apparatus of the second embodiment has further benefits, particularly relating to simulation and verification of the treatment, as will be explained in the following description of the specific features of the second embodiment.

As shown in Figure 12, the hollow body 50 comprises an inner portion 501 and an outer portion 502, the two portions being rotatable with respect to each other by appropriate mechanical interconnection. The collimator 4d (beam limiting device) is provided on the inner portion 501 of the hollow body, and an image detection device 100 is provided opposite to the collimator. The image detection device 100 may comprise a light sensing array which has a surface which converts the incident X-Ray or other radiation into light for detection by the light sensing array.

A beam stop 102 is also provided on the inner portion 501 in order to act as a counterbalance for the collimator 4d. Although the image detection device 100 is located opposite to the collimator 4d, it has a much lower weight than that of the collimator, and an additional counterbalancing weight is therefore preferred.

The outer portion 502 of the hollow body houses the radiotherapy source 4a,4b, which may be a 6MeV X-ray radiation source. This may be a straight through X-ray source 4a and LINAC 4b (as represented in Figures 10 to 12), but it may comprise an arrangement similar to that shown in Figure 3 including

a beam deflection unit. Again, a beam stop 104 is provided opposite to the MeV source to act as a counterbalancing weight to balance the outer portion 502 of the hollow body 50.

A KeV imaging radiation source SO is also mounted to the outer portion 502 of the hollow body, preferably adjacent the treatment source 4a, 4b. Since the outer portion 502 can rotate relatively to the inner portion 501 of the hollow body, either the treatment source 4a, 4b or the imaging source SO can be aligned with the collimator 4d. Furthermore, the imaging device 100 is preferably mounted on bearings 106 (only represented schematically) so as to allow movement of the imaging device 100 relatively to the inner portion 501 of the hollow body 50, so that movement is possible between a first position (Figure 12) in which the imaging device 100 is opposite the collimator 4d, and a second position (Figure 10) in which the imaging device 100 is offset from the first position. Alternatively, the image detecting device 100 may be mounted on its own drum arrangement rotatable relatively to the inner portion 501.

The operation of the device shown in Figures 10 to 12 will now be described. Figure 10 shows the device in an initial imaging mode of operation. The imaging device 100 is offset from the position opposite the collimator 4d, so that an image scanning operation may be carried out using an imaging beam IB which is not obstructed by the collimator 4d. Both portions of the hollow body 501, 502 may be rotated together in order to obtain images from a number of positions around the patient. The imaging source is preferably displaced from the treatment head 4a, 4b around the outer portion 502 only by an angle sufficient to ensure that the collimator 4d does not obstruct the path of the imaging beam IB during the imaging shown in Figure 10. By reducing the displacement of the two components to a minimum, the relative movement between the inner and outer portions 501, 502 of the drum is kept to a minimum.

Based on the detected images, the collimator settings for treatment from the selected positions around the patient 2 may be evaluated. In Figure 11, the imaging device 100 has been returned to the position opposite the collimator 4d. In addition, the outer portion of the hollow body has been rotated so that

the KeV imaging source 50 is now aligned with the collimator 4d. This enables verification of the collimator settings using the image sensing device (rather than by visual inspection). A verification beam VB is therefore transmitted through the collimator 4d. The collimator positions can be accurately verified as corresponding to the desired treatment. It is possible to omit the provision of movement of the image detection device 100 relatively to the inner portion 501 of the hollow body, if desired. For example, the image scanning may be provided by projecting the imaging beam IB through an open collimator, and only setting the collimator to limit the projection of the beam for verification of the treatment plan.

During the treatment procedure, shown in Figure 12, the treatment source 4a, 4b is aligned with the collimator 4d. The image detection device 100 provides simultaneous treatment verification. Again, the two portions 501,502 of the hollow body 50 rotate together to enable treatment from the selected angles around the patient 2.

The apparatus of this embodiment may be supplied with different equipment levels. For example, a basic system could be supplied to users who had previously found the cost of two separate units, namely the simulation apparatus and treatment apparatus described above, to be prohibitive. In this case, the apparatus could comprise only a treatment source 4 and simple rectangular collimator 4d. The initial localisation could be carried out by feel, as is already sometimes practised. Following this identification of the treatment area, treatment planning could be carried out by using a light source in place of the KeV imaging source, to provide visual adjustment of the treatment beam area. This system has the benefit of the integrated patient support 6, not requiring stepping of the patient through the treatment area, and enables at least basic visual treatment planning together with conventional radiotherapy treatment from a single machine. The use of a beam stop 102, 104 as a counterbalancing weight reduces the amount of shielding required for the treatment room, which reduces the installation costs. The installation is also simplified because of the use of a stationary patient support 6, which may therefore be a fixed part of the apparatus. Thus, this configuration can be

considered to provide a lowest cost complete radiotherapy apparatus for use in, for example, developing countries.

This system could be supplied or could be upgraded to include the KeV imaging source SO and image detector 100. This then enables more accurate treatment planning by enabling electronic image scanning. Furthermore, when an image detector 100 is provided, the possibility of simultaneous verification during treatment becomes possible, because the relative rotation of the two portions of the hollow body 501, 502 enables the imaging device 100 to be located opposite to the imaging source SO for imaging or opposite to the treatment source 4 for verification.

The use conventionally of two separate apparatus for localisation/simulation and for treatment has the effect that simulation of the treatment is carried out through a different collimator to that used for the treatment itself. The apparatus of this embodiment, in addition to reducing costs by providing a single collimator, also has the advantage that the treatment simulation is carried out using the same collimator as that used for the treatment itself. This enables the treatment beams to conform exactly with the simulated treatment, and differences in the beam shapes do not arise as a result of the different collimator configurations. Previously, it would not be considered appropriate to provide a MeV collimator in a simulator apparatus having a KeV imaging source.

A more advanced system, or a further upgrade, could include a Computer Tomography scanning system, to provide a more accurate evaluation of the tumour shape. The use of a multileaf collimator would then enable a treatment program to be sufficiently advanced to warrant this scanning system.

The radiotherapy system of this invention may be provided as a transportable system as a result of the unitary construction. The use of the beam stops 102, 104 should enable sufficient shielding to be possible in a lorry compartment, so that the system may be provided as an assembled transportable unit. This may enable the system to be shared between regions which would not individually have the finances or required level of expertise to install and operate such a system.

The inner portion of the hollow body 501 may include an opening 108 (shown in Figure 10 only) which, when aligned with the treatment source (and imaging source), enables servicing of the treatment source (and imaging source) without removal of the collimator. Previous systems have required
5 removal of the collimator in order to gain access to the treatment head, which requires regular servicing. As explained above, a MeV multi-leaf collimator comprises heavy components to achieve the required level of beam absorption, and may typically weigh approximately ½ tonne. The apparatus of the second embodiment therefore reduces servicing costs, avoiding the need to remove the
10 collimator. The opening 108 may also function as a passageway for the imaging beam IB through the inner portion 501 of the hollow body, as shown in Figure 10.

The different levels of equipment enable the system to be adapted to any level of treatment, from a basic system which would normally be used for
15 palliative treatment, to an advanced Cone Beam Computer Tomography system. One treatment technique, under development by the applicant, may be applied by the apparatus of either embodiment of the invention, and is discussed in the following.

Various radiotherapy treatment techniques have evolved using apparatus
20 similar to that shown in Figure 1.

One such technique, tomotherapy, involves a slice by slice treatment (and image scanning) of a tumour. A required dose distribution pattern is obtained for each slice and this dose is administered by the application of a fan shaped beam. The treatment of each slice involves a single gantry rotation
25 with different fan shaped beams being applied at different gantry angles. The patient is stepped through the radiotherapy apparatus to enable treatment of the entire treatment area. Although a very accurate dose distribution pattern may be obtained, problems may arise in matching the radiation fields of adjacent slices and a prolonged treatment time may result if a large number of
30 slices are involved.

This invention is concerned with an alternative approach in which the radiotherapy beam covers substantially the entire tumour area. Thus, instead

of a fan beam being propagated which penetrates into a slice of the patient, the beam covers a two dimensional, for example square, area and the envelope of the radiation beam may be considered to be a square based pyramid, for example. As a result, a single rotation of the gantry, or in the case of the present invention of the drum, enables a dose to be administered to the entire treatment volume of the patient. The distribution pattern of the two dimensional area covered by the beam is controlled by a multi-leaf collimator or other collimator (beam limiting device) which provides two dimensional limitation of the beam shape, for example into a rectangular shape of the selected dimensions.

A proposed treatment technique which operates according to this principle delivers these beams from a limited number, for example 5 to 7, of directions. Each of these beams has its intensity modulated for each elemental portion of the beam area with the result that a sufficiently accurate dose distribution may be obtained from the limited number of beam delivery positions. However, each of the limited number of beams will have a complex dose distribution pattern which may take a long time to administer. This is particularly so as the intensity is varied by altering the duty cycle of the leaves of the multi-leaf collimator. Furthermore, in view of the limited number of beams to be generated, an optimum distribution pattern is desired for each of those beams to enable the overall dose distribution to have the required accuracy. In view of this, it is desirable to alter the adjust patient position between beam deliveries since an oblique entry angle may be desired, or an oblique angle may be required for the entire treatment. As a result, it may be necessary to provide an area of clearance around the patient to enable the operating staff to carry out set up positioning during the treatment procedure. Although the apparatus according to the invention may be used to implement such a treatment technique, for example the patient support 6 may be rotatable about the support member 8, the apparatus of the invention is more suited to a treatment technique which does not require patient manipulation during the treatment procedure. This is a result of the enclosed nature of the apparatus according to the invention. For example, the technique above may be

employed, without providing oblique entry angles.

As explained above, the apparatus of the invention and particularly the second embodiment is suitable for a range of different treatment techniques according to the different types of imaging system and treatment heads that
5 may be employed. However, in the field of advanced treatment techniques, involving computer generated scanning images and complex beam distribution patterns, the apparatus according to the invention is particularly suited to an alternative treatment technique currently being developed by the applicant.

This new technique uses multi-leaf collimator shaped fields which
10 change shape during rotation of the drum in order to deliver the dose to the treatment target. The fields have a fixed intensity during the rotation of the drum and a number of drum rotations are required in order to build up a complex intensity pattern. Thus, the treatment is delivered as a number of arcs each with a different succession of field shapes, and the shapes are defined
15 typically every 5° . The number of arcs required in order to define the intensity distribution pattern may be of the order of 5 and a single rotation of the hollow body may take of the order of 4 minutes. In particular, during the rotation of the hollow body, the multi-leaf collimator does not carry out intensity modulation but merely changes the shape of the beam delivered.

20 The overall intensity distribution must be reduced into individual intensity distributions for each beam delivery gantry angle. Each of these individual distributions is then reduced into portions which correspond to the beam shapes which may be delivered by the leaves of the multi-leaf collimator. It may be required to rotate the collimator between angles of the hollow body
25 since there are certain collimator angles along which the multi-leaf collimator leaves best conform to the required field shape.

Once the intensity distribution for a particular leaf of the multi-leaf collimator is known for a particular position, it is necessary to define the intensity distribution as a combination of intensity patterns that can be applied
30 by the multi leaf collimator (namely continuous strips) which may be successively applied.

This principle is best explained with reference to Figure 13. Figure 13

part (a) shows a desired intensity profile, to be delivered from a certain drum angle, along a strip defined by one pair of leaves of a multi-leaf collimator. As shown in Figure 13 part (b), the desired intensity may be approximated as a stepped profile which in this case has three different intensity levels. In order to reduce this intensity profile into the profile to be applied by successive leaf positions during successive arcs of the treatment, there are a number of possible solutions. Each of these solutions is shown in Figure 13 part (c). There is also freedom to choose the order in which the constituent portions are applied.

The fact that there are a number of ways of obtaining the desired intensity profile over the number of arcs enables leaf positions to be chosen which reduce the movement of the leaves of the multi-leaf collimator during the rotation of the drum. The process shown in Figure 13 assumes that the same intensity is applied for each arc of treatment. However, different intensities may be applied during the different drum rotations and this will alter the manner in which the desired intensity profile is decomposed.

Some leaf pairs will need to be closed at certain points around the arc and it is arranged so that the closure of the two leaves is located at the edge of the collimator area, since the closure of two leaves cannot completely prevent the passage of radiation. To prevent excessive movement of the leaves, the previous and following decomposition pattern will be appropriately selected to minimise the required travel path of the leaves.

For arcs with similar field shapes at all angles, high dose rate and high speed of drum rotation can be applied resulting in less overall beam time.

An advantage of this system is that there is no rotation of the patient support 6 during the rotation of the drum. There is also no theoretical reason why an oblique entry angle should be required for the treatment, although this may be desirable as a result of planning considerations not related to the required dose distribution. Since the treatment does not require movement of the patient during rotation of the drum, there is no need for significant access to be provided to the patient and the arrangement of the apparatus according to the invention is particularly suited to this treatment technique.

The apparatus of the invention therefore preferably includes controlling means (not shown) for providing a first beam of a first fixed intensity and for controlling the multi-leaf collimator during rotation of the drum, and for providing a second beam of a second fixed intensity and controlling the multi-leaf collimator during the second rotation of the drum. The first and second intensities may be the same, as in the situation described with reference to Figure 13, although different intensities may be adopted.

Where the apparatus of the invention is for curative treatment and an advanced treatment is to be administered, the apparatus is thus preferably adapted to the above described advanced treatment technique. In such a case, the controlling means must apply, in succession, a number of fixed intensity beams to correspond to the number of rotation arcs required. This depends upon the dose intensity distribution to be administered.

From reading the present disclosure, other modifications and variations will be apparent to persons skilled in the art. Such modifications and variations may involve other features which are already known in the art and which may be used instead of or in addition to features already described herein. Although claims have been formulated in this application to particular combinations of features, it should be understood that the scope of the disclosure of the present application also includes any novel feature or combination of features disclosed herein either explicitly or implicitly, whether or not relating to the same invention as presently claimed in any claim and whether or not it mitigates any or all of the same technical problems as does the presently claimed invention. The applicants hereby give notice that new claims may be formulated to such features and/or combinations of such features during prosecution of the present application or of any further application derived therefrom.

CLAIMS

1. Apparatus for treating a patient by exposing a treatment area of the patient to radiation, the apparatus comprising:

5 a support;

a hollow body having a central aperture which defines a passageway extending through the body, the hollow body being mounted to the support so as to be rotatable about a central axis of the hollow body;

10 a radiotherapy source mounted to the hollow body so as to be rotatable with the hollow body and for projecting a radiotherapy beam within the passageway which crosses the central axis of the hollow body;

a beam limiting device for controllably partially limiting the projected area of the beam; and

15 a patient support for receiving the patient and which extends at least partly through the passageway and which is positioned such that an unlimited projection area of the beam substantially covers the treatment area of the patient.

2. Apparatus as claimed in claim 1, wherein the radiotherapy source
20 includes a linear particle accelerator disposed within the hollow body which extends in a plane which lies substantially perpendicular to a longitudinal axis of the patient support.

3. Apparatus as claimed in claim 2, wherein the passageway is
25 substantially cylindrical and the apparatus further comprising deflecting means for deflecting the particle beam produced by the linear accelerator to a substantially radial direction with respect to the cylindrical passageway.

4. Apparatus as claimed in any preceding claim, wherein the patient
30 support is coupled to the hollow body, the coupling being arranged to allow angular movement of the patient support about the rotation axis of the hollow body and means is provided for maintaining the patient support at a

substantially constant attitude with respect to a fixed reference plane.

5 5. Apparatus as claimed in claim 4, wherein the coupling is arranged to allow translational movement of the patient support with respect to the body in one or more directions parallel to or perpendicular to an axis of projection of the beam.

10 6. Apparatus as claimed in any preceding claim, further comprising an imaging radiation source which is mounted on the hollow body, and a radiation detection device mounted on the hollow body at a location which is opposite to the imaging radiation source.

15 7. Apparatus as claimed in any one of claims 1 to 3, wherein the hollow body comprises an inner portion within which is defined the passageway, and an outer portion, the inner and outer portions being rotatable with respect to each other, the radiotherapy source being mounted on the outer portion of the hollow body, and the beam limiting device being mounted on the inner portion of the hollow body.

20 8. Apparatus as claimed in claim 7, wherein an imaging source is mounted on the outer portion of the hollow body at a position displaced from the radiotherapy source, the relative rotation between the two portions enabling the radiotherapy source or the imaging source to be aligned with the beam limiting device.

25 9. Apparatus as claimed in claim 8, wherein the imaging source comprises a light source.

30 10. Apparatus as claimed in claim 8, wherein the imaging source comprises an X-ray source, and the apparatus further comprises an X-ray image detecting device mounted on the inner portion of the hollow body, opposite to the beam limiting device.

11. Apparatus as claimed in claim 10, wherein the X-ray image detecting device is slidably received by the inner portion of the hollow body so as to be slidable between a first position opposite to the beam limiting device and a second position displaced from the first position, the angle of displacement between the two positions corresponding to the angle of displacement between the imaging source and the radiotherapy source.

12. Apparatus as claimed in any preceding claim, in which the beam limiting device comprises a multi-leaf collimator.

13. Apparatus as claimed in any preceding claim, comprising controlling means for controlling the radiotherapy source to provide a first beam of a first fixed intensity and controlling the beam limiting device to selectively limit the projection area of the beam at a plurality of positions of the hollow body during a first rotation of the hollow body, and for controlling the radiotherapy source to provide a second beam of a second fixed intensity and controlling the beam limiting device to selectively limit the projection area of the second beam at a plurality of positions of the hollow body during a second rotation of the hollow body.

14. Apparatus as claimed in any proceeding claim for treatment by radiotherapy, the treatment involving administering a plurality of arc treatments, each arc treatment corresponding to a rotation of the hollow body and each arc treatment involving administering a beam of a respective fixed intensity, which beam changes shape as the hollow body rotates, the change in shape being governed by the beam limiting device.

15. A transportable radiotherapy system comprising a vehicle having a compartment housing an apparatus for treating a patient as claimed in any preceding claim.

16. A method of operating an apparatus in accordance with any

preceding claim, comprising:

driving the radiotherapy source to produce a radiotherapy beam of a first fixed intensity;

5 rotating the hollow body so that it follows a first arc and controlling the beam limiting device so as to alter the projection area of the beam during the first rotation of the hollow body;

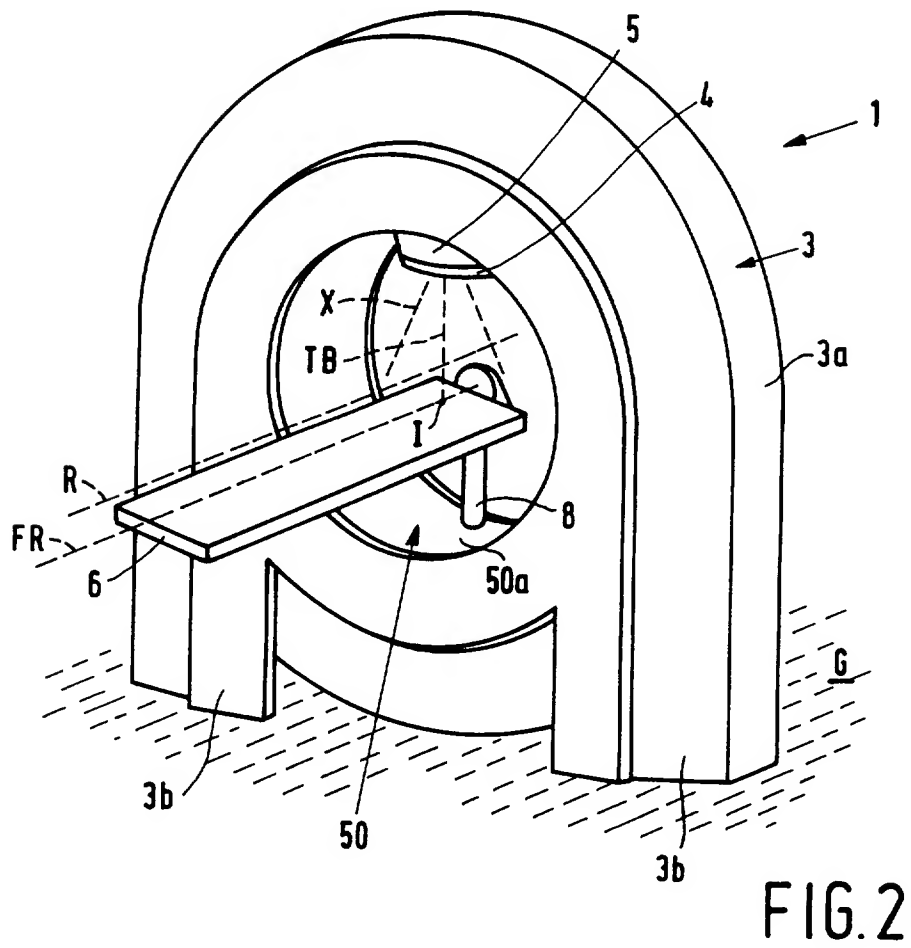
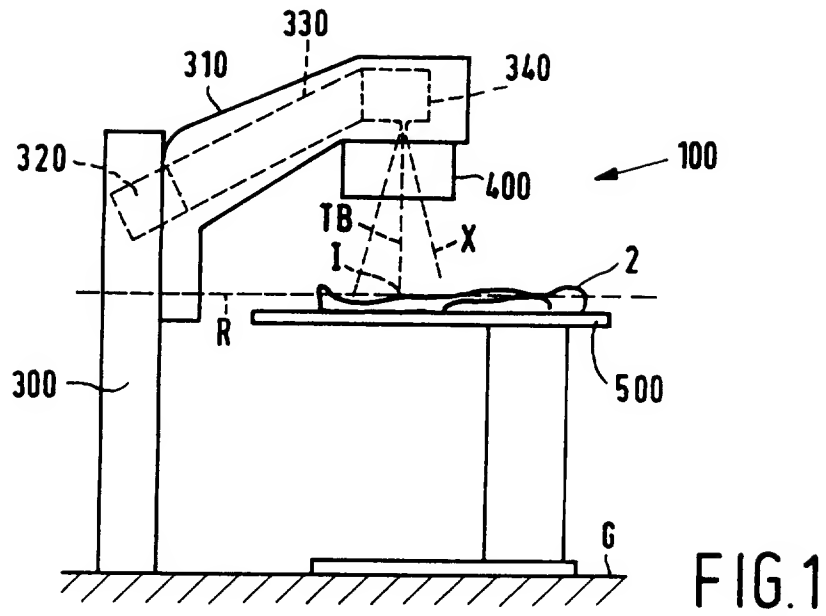
driving the radiotherapy source to produce a radiotherapy beam of a second fixed intensity;

10 rotating the hollow body so that it follows a second arc which substantially corresponds to the first arc and controlling the beam limiting device so as to alter the projection area of the beam during the second rotation of the hollow body.

15 17. A method as claimed in Claim 16, wherein first fixed intensity is equal to the second fixed intensity.

18. A method as claimed in Claim 16 or 17, wherein three or more hollow body rotations are provided.

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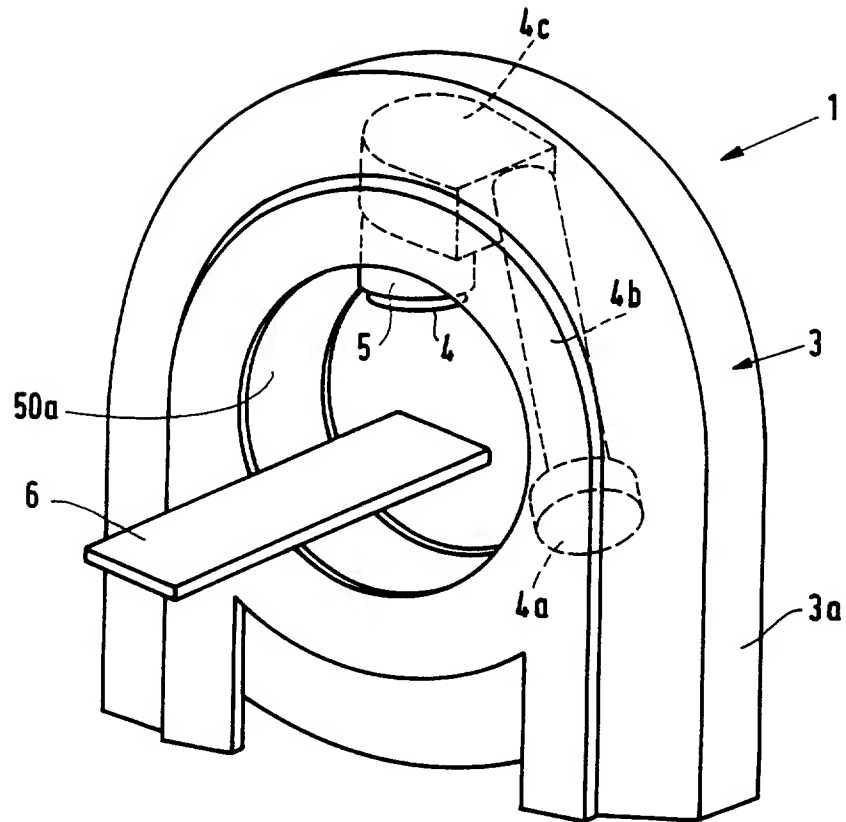


FIG. 3

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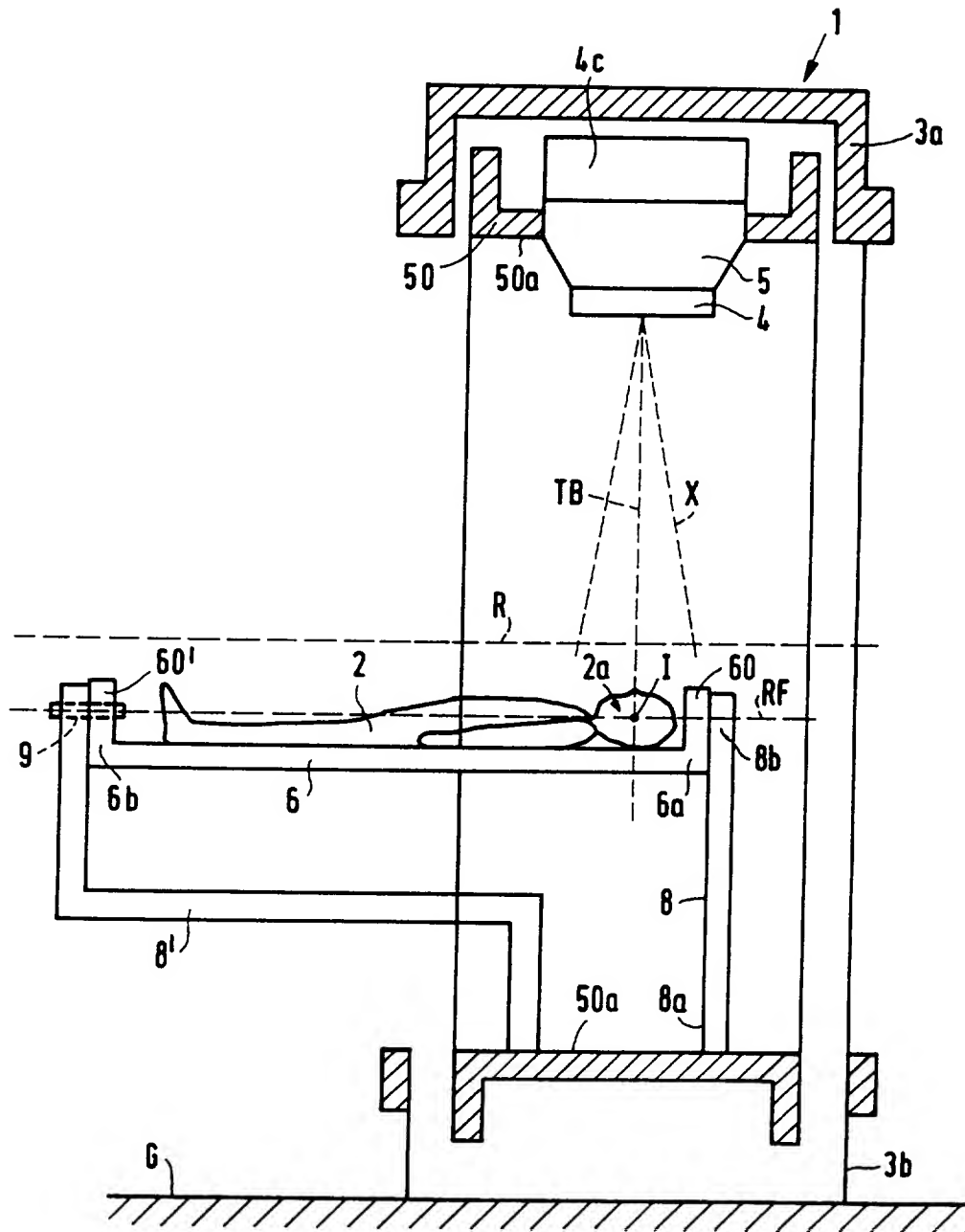


FIG. 4

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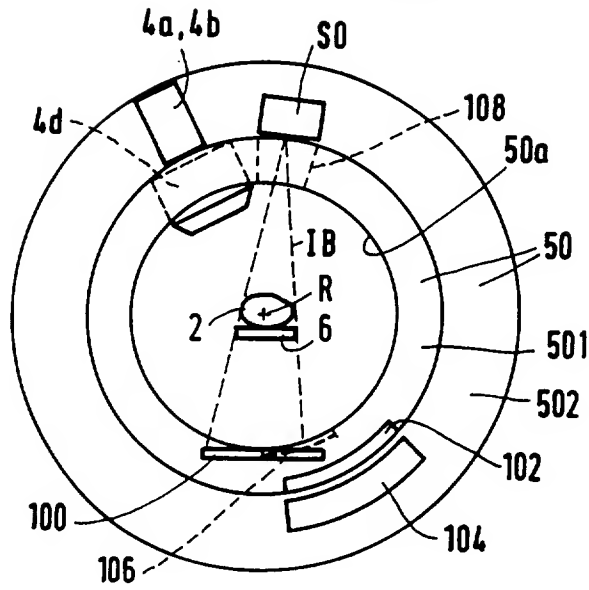


FIG. 10

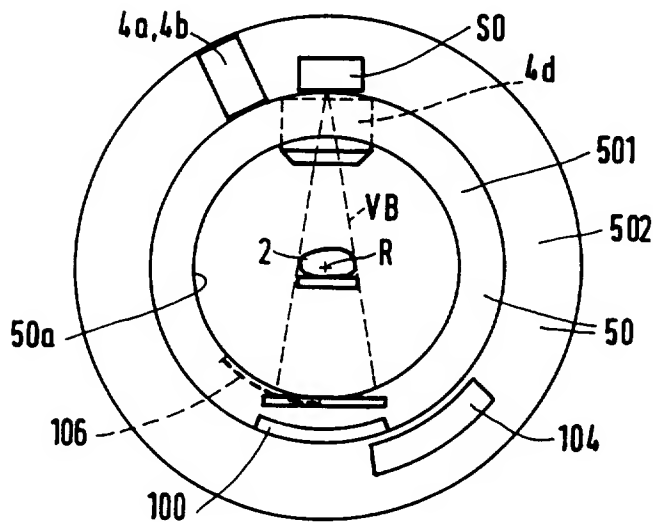


FIG. 11

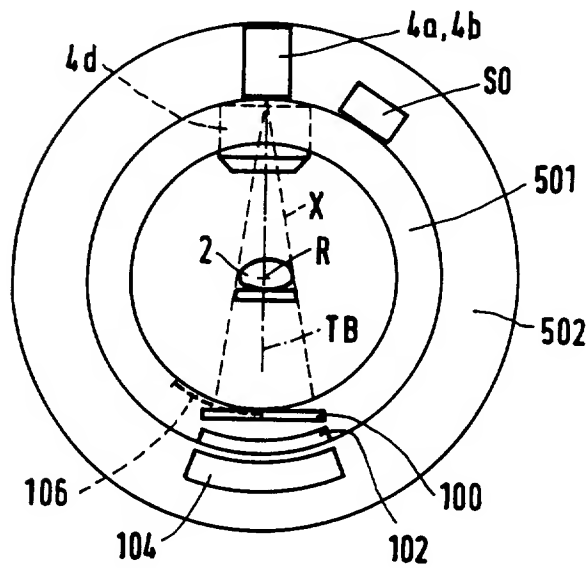


FIG. 12

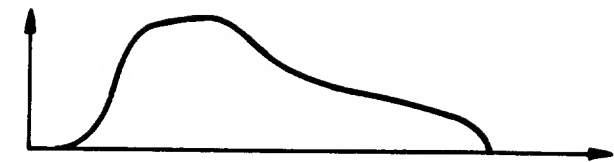


FIG.13a

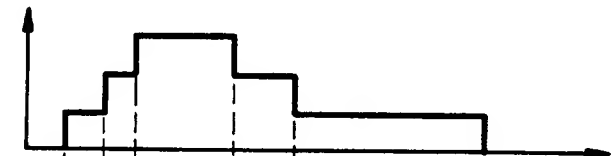


FIG.13b

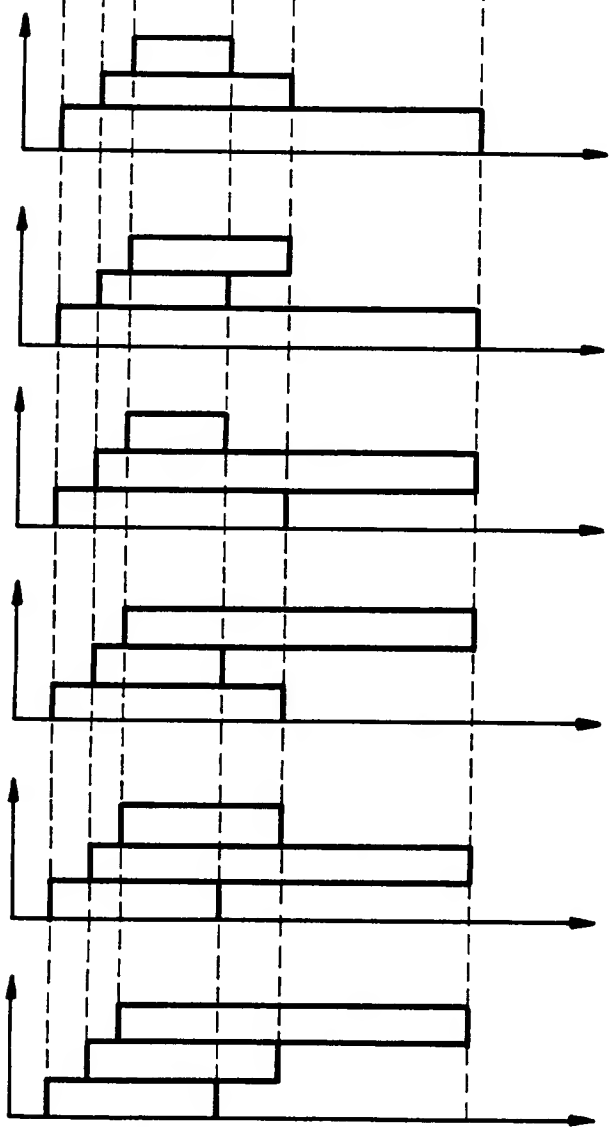


FIG.13c

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 96/01046

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61N 5/01, A61N 5/10, A61B 6/00

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9428971 A2 (WISCONSIN ALUMNI RESEARCH FOUNDATION), 22 December 1994 (22.12.94), page 5, line 7 - line 34; page 6, line 14 - line 18; page 13, line 24 - line 34	1-6,12-18
A	--	7-11
P,X	FR 2728471 A1 (GE MEDICAL SYSTEMS SA SOCIETE ANONYME-FR.), 28 June 1996 (28.06.96), abstract	1-6,12-18
A	FR 2529088 A1 (MECANIQUE ET CONCEPTIONS INDUSTRIELLES MODERNES (MCIM).-FR.), 30 December 1983 (30.12.83), abstract	4,5
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☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5448607 A (G.W. ELECTRONICS N.V. ET AL.), 5 Sept 1995 (05.09.95), abstract --	15
A	US 4649560 A (J.K. GRADY), 10 March 1987 (10.03.87), figure I, abstract -- -----	1-18

INTERNATIONAL SEARCH REPORT
Information on patent family members

03/02/97

International application No.

PCT/IB 96/01046

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WO-A2- 9428971	22/12/94	EP-A- 0703805 IL-D- 109960 JP-T- 8511452 US-A- 5442675 US-A- 5548627	03/04/96 00/00/00 03/12/96 15/08/95 20/08/96
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FR-A1- 2529088	30/12/83	NONE	
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US-A- 5448607	05/09/95	AU-A- 1910895 DE-T- 19581543 WO-A- 9521570	29/08/95 16/01/97 17/08/95
US-A- 4649560	10/03/87	CA-A- 1231786 DE-A- 3500759 FR-A- 2558716 GB-A,B- 2154410	19/01/88 08/08/85 02/08/85 04/09/85



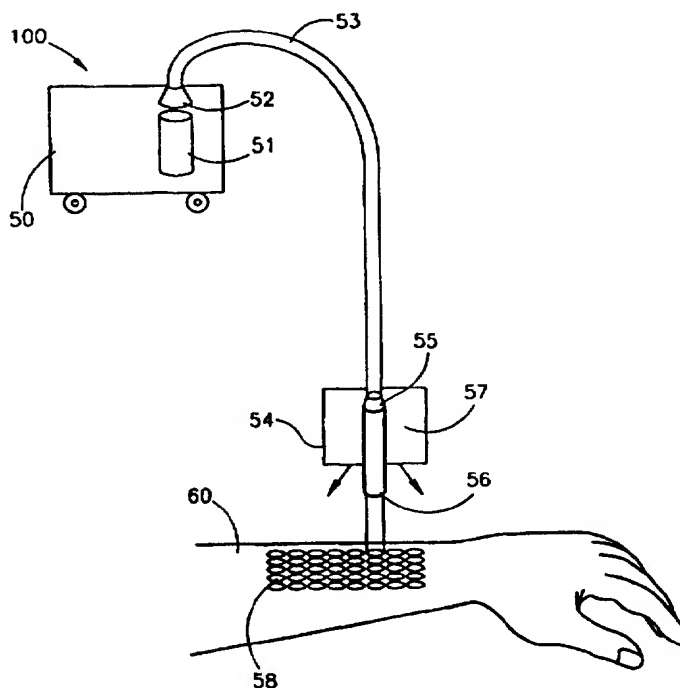
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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			(43) International Publication Date: 26 June 1997 (26.06.97)
(21) International Application Number: PCT/IL96/00184		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 18 December 1996 (18.12.96)			
(30) Priority Data: 60/008,802 18 December 1995 (18.12.95) US 118229 12 May 1996 (12.05.96) IL 119051 11 August 1996 (11.08.96) IL			
(71) Applicant: LASER INDUSTRIES LTD. [IL/IL]; Atidim Science Based Industrial Park, Neve Sharett, P.O. Box 13135, 61131 Tel Aviv (IL).		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(72) Inventors: SLATKINE, Michael; 59 Brenner Street, 46427 Herzlia (IL). WALDMAN, Amir; 20 Revi Street, 45296 Hod Hasharon (IL). BRAUDE, Ofer; 189 Aluf David Street, 52222 Ramat Gan (IL). ROZENBERG, Zvi; 2 Hashikma Street, 90805 Mevasseret Zion (IL). KLEIN, Arie; 34 Hagalil Street, 44233 Kfar Saba (IL).			
(74) Agent: A. TALLY EITAN-ZEEV PEARL & CO.; Law Offices, Lumir House, 22 Maskit Street, 46733 Herzlia (IL).			

(54) Title: HAIR REMOVAL BY SELECTIVE PHOTOTHERMOLYSIS WITH AN ALEXANDRITE LASER

(57) Abstract

This invention is a hair removal by using an Alexandrite laser (50) emitting energy between 0.2 joules to 40 joules per pulse to provide an energy fluence between 15 joules and 70 joules per centimeter square, and having a pulse duration of between 100 microseconds and 10 milliseconds. A scanner (57) may be used to direct the laser beam on the tissue (60). The skin in the area to be irradiated may be shaved prior to exposure to laser treatment, and may be also covered by a protective substance serving as a heat sink (42).



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HAIR REMOVAL BY SELECTIVE PHOTOTHERMOLYSIS WITH AN ALEXANDRITE LASER

5

FIELD OF THE INVENTION

The present invention relates to laser surgery apparatus and method to remove hair that directs pulsed laser beams from an Alexandrite laser to a protective substance that protects an external surface of skin against damage from overheating and that provides markings to indicate where the impingement takes place.

10

BACKGROUND OF THE INVENTION

Treatment of skin with lasers have been the subject of study since the early 1960s. A variety of lasers have been used in dermatologic practice. Different lasers are primarily distinguished by a wavelength of the light produced, measured in nanometers, such as the XeF excimer (351 nm), argon (488 nm, 514 nm), ruby (694 nm), Nd:YAG (1060 nm), and CO₂ (10,600 nm) lasers.

15

Photothermolysis of skin has been demonstrated using dye laser pulses and Q-switched ruby laser pulses. It has been found that radiation from Q-switched ruby lasers deeply penetrates the epidermis and dermis. It has also been found that application of ruby red laser energy can cause depigmentation of the skin as well as significant follicular damage to the extent that the hair will fall out.

20

The Q-switched ruby laser has been used for the treatment of tattoos, pigmented lesions, and conventional ruby lasers have been used to treat epidermal and dermal pigmented lesions. Studies based on experimentation with Q-switched ruby lasers, as well as other lasers, have reported skin depigmentation and temporary hair loss.

25

The use of lasers for non-invasive hair removal has been disclosed in U.S. Patent No. 5,059,192, issued October 22, 1991 to Nardo Zaias, entitled METHOD OF HAIR DEPILATION. This patent teaches the use of a pulsed ruby laser as the preferred embodiment. The ruby laser radiation (694 nm wavelength) penetrates deep into tissue and is relatively well absorbed by melanin to cause thermal damage to dark, melanin rich hair shafts and follicles.

30

U.S. Patent No 5,226,907, issued July 13, 1993 to Nikoli Tankovich, entitled HAIR REMOVAL DEVICE AND METHOD and U.S. Patent No. 5,425,728,

35

issued June 20, 1995 to Nikoli Tankovich, entitled HAIR REMOVAL AND METHOD teach the use of a CO₂ pulse laser and a Nd:YAG laser, among other types of lasers, to effect hair removal in conjunction with light absorbing oil used to stain hair.

5 The Nd:YAG laser is limited to relatively low energy levels at affordable commercial production costs. It is effective only for highly absorptive hairs, usually stained for this purpose. Energy levels adequate for hair removal with bare hairs makes it impractical to use an Nd:YAG laser.

10 Large pulsed ruby lasers are capable of delivering very high energy levels -- as high as 40J. As a result, they can attain the energy fluences of 15 - 70J/cm² necessary for hair removal. However, ruby lasers can be fired only at a very low repetition rate -- approximately 1 pulse per second (pps). This limits the benefit of using a scanner such as that described in U.S. Patent No. 5,411,502 to Eliezer Zair and the computerized pulsed generator (CPG) scanner, commercially
15 available from Coherent Inc. of California, USA. This low repetition rate is too low to cover large treated areas as legs and hands in a reasonable time. A 10 x 30cm² area (one leg) would require some 1200 pulses, each pulse covering an area of 0.25cm² (typical for hair removal with a 5 Joules laser). Assuming a repetition rate of 1pps, this leads to 20 minutes for a single leg, or over 1 hour for
20 two legs and two hands. This considerably limits the number of patients treatable for hair removal with the expensive laser.

 Another drawback of pulsed ruby lasers is their limited pulse time duration. Ruby lasers operated in their free running modes can usually attain a maximum time duration of 300-1000 microseconds. Extending the pulse duration to 1 - 10
25 milliseconds is almost impractical. On the other hand, it would be desirable to operate ruby lasers at pulse durations of 1 - 10 milliseconds in most cases of hair removal because of hair follicle diameters being of over 100 microns.

 A third drawback of ruby lasers is their size due to their low efficacy. A 5 Joules, 1pps ruby laser may typically be of 150cm x 70cm x 70cm size. A 25
30 Joule laser may weigh over 400 kilograms.

 U.S. Patent No. 5,290,273, issued March 1, 1994 to Oon Tan, entitled LASER TREATMENT METHOD FOR REMOVING PIGMENT CONTAINING LESIONS FROM THE SKIN OF A LIVING HUMAN and U.S. Patent No. 5,217,455, issued June 9, 1993 to Oon Tan, entitled LASER TREATMENT
35 METHOD FOR REMOVING PIGMENTATIONS, LESIONS, AND

ABNORMALITIES FROM THE SKIN OF A LIVING PERSON, teach the use of an Alexandrite laser instead of a ruby laser to treat pigmentation, lesions and skin abnormalities. Both teach that before and after irradiation, the area irradiated should be checked for the presence of absence of adhexac (skin appendages) such as hairs. If a hair loss condition is observed, then the energy density from the laser radiation should be decreased for subsequent treatments. The pulse duration is 10-300 nanoseconds.

Skin treatment employing laser based systems, usually pulsed laser based systems is well known in the art. Such laser based systems are used inter alia for cutaneous vascular lesions treatment and for hair removal, the latter application being described for example in U.S. Patents Nos. 5,059,192 to Zais and 5,226,907 to Tankovich.

As is also well known in the art, the operation of laser based systems for cutaneous treatment is more effective when the tissue is cooled. Examples for prior art devices for cooling the skin during laser treatment are U.S. Patent 5,057,104, U.S. Patent 5,282,797 and U.S. 5,486,172 to Chess specifically designed for cutaneous vascular lesions treatments and U.S. Patent No. 5,344,418 to Ghaffari.

A major disadvantage of prior art laser based systems for cutaneous treatment is that the operation of the laser is not visible to the physician carrying the treatment, thus he can not be sure that the laser covered the entire area to be treated. This results in an inhomogeneous treatment of the skin, such as an inhomogeneous removal of hair from the patient skin in the case of hair removal treatment.

25

SUMMARY OF THE INVENTION

One aspect of the invention is to generate at least one pulsed Alexandrite laser beam that travels in a path to a hair follicle. The beam is of sufficient energy and pulse duration to damage hair follicle papilla.

Another aspect of the invention is to provide a protective substance in the path to help protect an external surface of the skin against overheating otherwise arising from the pulsed laser beam.

For non-invasive surgery, this protective substance may be a cooling gel applied to the external surface of the skin to cool the external surface and thereby prevent overheating. For invasive surface, this protective substance may be energy absorbing or reflecting particles that block the laser radiation from penetrating to the external surface of the skin.

Preferably, a plurality of markings are provided that indicate the locations on which the laser beam impinges. The markings may each vaporize upon impingement of a laser beam thereupon or be spaced away so that the laser beam will not impinge them.

The protective substance may cool the skin during laser treatment. This substance may be contained within an enclosure which in turn may have thereon the markings. The enclosure is flexible preferably formed substantially of polyethylene, polypropylene or polycarbonate. This enclosure may have a peelable cover so as to enable direct contact between the gel and the area of the skin of a patient. Preferably, the edge of the enclosure exposed by peeling the peelable cover includes an adhesive material for attaching the enclosure to the patient skin.

The markings may be physically placed on the area of the skin to be treated or adjacent thereto or the markings may be placed over the area of the skin to be treated such as on a transparent sheet disposed intermediate the laser beam and the skin. Alternately, the markings may be projected onto the area of the skin to be treated.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, reference is made to the following description and accompanying drawings, while the scope of the invention is set forth in the appended claims.

5 Fig. 1 is a cross-sectional view of three hair shafts showing the stages of the hair cycle;

 Fig. 2 is a cross-sectional view of a hair follicle after the top has been cut, but prior to application of laser pulse;

10 Fig. 3 is a cross-sectional view of the follicle of FIG. 2 after laser treatment, showing the damaged hair germ;

 Fig. 4 is a schematic representation showing the impingement and skin penetration with an Alexandrite laser beam in effecting hair removal;

 Fig. 5A shows a schematic pictorial representation of a hair follicle;

15 Fig. 5B shows a graph representing the results of a computer simulation of photothermolysis with an Alexandrite laser beam, aligned with the follicle of Fig. 5A;

 Fig. 6 is a graphical representation of the absorption spectrum of melanin and oxyhemoglobin;

20 Fig. 7 is a schematic representation of the beam of an Alexandrite laser interacting with tissue in accordance with the invention;

 Fig. 8 is a schematic representation of an Alexandrite laser apparatus for hair depilation according to the present invention;

25 Figs. 9A and 9B are schematic representations of arrangements showing a plurality of markings in accordance with two alternative embodiments of the invention;

 Figs. 10A - 10C are schematic representations of progressive views illustrating the operation of the apparatus of Fig. 9A;

 Fig. 11A is a schematic representation of a cooling apparatus in accordance with an embodiment of the invention;

30 Fig. 11B is a schematic representation of a cooling apparatus in accordance with another embodiment of the invention;

 Fig. 12 is a schematic representation of a system for hair removal in accordance with still another embodiment of the invention;

35 Fig. 13 is a schematic representation of a marking projection system in accordance with a further embodiment of the invention;

Fig. 14A is a schematic representation of a cooling apparatus in accordance with yet another embodiment of the invention; and

Fig. 14B illustrates the cooling apparatus of Fig. 14A in operation.

5

DESCRIPTION OF THE PREFERRED EMBODIMENT

Fig. 1 shows a hair shaft 10 which has been cut down near the surface of the skin 12. The shaft 10 extends down to the follicle 14 which at the anagen stage of the hair cycle joins the papilla 16. Destruction of the papilla 16 is
10 necessary to prevent hair regrowth.

After growing for a period of time that is different for different parts of the human body in the anagen stage, the hair shaft 10 enters the catagen stage represented by hair shaft 20 wherein the papilla 22 separates from the base of the follicle 24. The catagen stage lasts only a few weeks.

15 Hair shaft 30 represents the telogen stage of the hair cycle wherein the papilla 32 completely separates from the follicle 34 and forms a new secondary hair germ which will repeat the cycle. The telogen stage also lasts for a period of time that depends on the part of the body. For arms, it is about three months.

To assure sufficient injury to the papilla 32 at the telogen stage as well as
20 the papilla 16 at the anagen stage, use of a laser with sufficient energy and depth of penetration is necessary to achieve sufficient melanosomal destruction. Cutting of the hair shaft down to the skin 12 in advance of lasing provides two important functions of the treatment process. First, the tip 18 of the hair shaft 10 allows the laser operator to position the laser substantially vertically over the hair
25 follicle opening such that an optimum location for aiming the laser pulse to strike the papilla 16 is obtained. Second, the reduction of excess hair eliminates additional scattering and absorption of other radiant energy contained in the pulse.

Fig. 2 shows an enlarged view of the hair shaft 10 prior to treatment,
30 wherein the follicle 14 and papilla 16 are normal in appearance in the anagen stage.

Fig. 3 shows the treatment after the laser pulse has been applied to the follicle 14 and the resulting effect on the papilla 16.

35 Application of the laser pulse to the follicle and the papilla causes photothermolysis which provides melanosomal disruption, including vaporization

of the melanin in the follicle 14 and papilla 16, as well as vacuolation, edema, gas bubbles and protein denaturation. When the pulse applied is of sufficient energy level, these effects seriously injure the hair follicle and papilla, thereby damaging the hair germ which causes hair regrowth. The hair follicle 14 may extend into the
5 reticular dermis up to 3 mm from the skin surface.

Turning to Fig. 4, the use of an Alexandrite laser beam 44 (see Fig. 7) is shown for non-invasive hair removal by selective photothermolysis.

In accordance with the process of selective photothermolysis, the pulse duration time should be shorter than the thermal relaxation time of the follicle.
10 The thermal relaxation time is defined as the time it takes for a structure to cool to 50% of its peak temperature immediately after laser exposure. The calculated thermal relaxation time for hair shafts and follicle has been found to be approximately 1 - 10 milliseconds.

Figs. 5A and 5B show a computer simulation that is based on a "MONTE
15 CARLO" statistical model of light scattering in the skin, see M.J.C. Van Gemert et al., "Skin Optics", IEEE translation on Biomedical Engineering, Vol. 36, pp. 1146-1150 (1989). The temperature distribution shows follicle destruction.

Fig. 5A illustrates a schematic cross section in a hair follicle. Fig. 5B illustrates a graph of the simulated energy density distribution curve. The
20 horizontal axis of the graph represents the value of the simulated energy density. The vertical axis of the graph represents the depth within the skin and is roughly aligned with the cross section of the follicle of Fig. 5A. The numbers along the curve of the graph of Fig. 5B roughly represent the simulated temperature at the corresponding depth values along the vertical axis of the graph.

25 Different types of hair and hair color will require variations in the energy dosage to effect permanent hair removal. Generally, darker hair will induce higher light absorption, therefore a lower dosage may be required.

As shown graphically in Fig. 6, the Alexandrite laser emits radiation at 755 nm. Its emitted beam absorption in tissue is higher than with a ruby laser
30 (approximately 4 times higher). As a result, general tissue heating is higher, which may necessitate tissue cooling in contrast to the case of superficial heating with a ruby laser. Also, melanin absorption of Alexandrite laser radiation is lower than for ruby laser radiation, thus reducing the amount of hair shaft heating and thus laser effectiveness. However, such advantages of the ruby laser tissue
35 effects over the Alexandrite laser tissue effects is offset by the very high energy

levels attainable with small size, high repetition rate attainable with Alexandrite lasers.

5 According to an alternative embodiment of the present invention, the Alexandrite laser energy is absorbed at least partly by a stain added to the hair itself or by a stained lotion introduced into the hair follicle. The stain or stained lotion absorbs in the 755 nm wavelength. Such a stain or stained lotion may, for instance, be black or blue but not the color of the Alexandrite frequency of near infrared.

10 The following table provides a qualitative comparison between Alexandrite and ruby laser for use for hair removal.

QUALITATIVE COMPARISON BETWEEN ALEXANDRITE AND RUBY LASER FOR HAIR REMOVAL

	TECHNOLOGY		
5	LASER	RUBY	ALEXANDRITE
	COLOR	RED (694 NM)	INFRARED (755 NM)
	ENERGY PER PULSE WITH A SMALL- MEDIUM SIZE LASER	LOW	HIGH
	MAXIMUM PULSE DURATION IN FREE RUNNING MODE	UP TO 1 MILLISECOND (PRACTICAL)	LONGER (BETTER FOR HAIR REMOVAL)
10	<hr/> TISSUE INTERACTION <hr/>		
	HAIR REMOVAL CAPABILITY	GOOD	GOOD
	DAMAGE TO EXTERNAL SKIN LAYER	HAVE TO BE CAREFUL WITH DARKER SKIN	SMALLER RISK TO DAMAGE DARKER SKIN - HIGHER ABSORPTION BY BLOOD VESSELS
15	<hr/> TREATMENT STRATEGY AND ECONOMY <hr/>		
	USE OF A SCANNER	NO NEED; MANUAL WORK	ADVANTAGEOUS
	COOLING REQUIREMENT	STRINGENT ONLY FOR EPIDERMIS	CONSIDERABLY LESS STRINGENT FOR EPIDERMIS. NEED FOR DERMIS
	SPEED OF PROCEDURE	VERY SLOW	VERY FAST
	POSSIBLE NUMBER OF PATIENTS PER DAY	SMALL	LARGE
20			

Turning to Fig. 7, the laser delivery system 40 delivers a fast repetition rate pulses of laser radiation to the tissue that has been previously shaved.

Preferably, the laser beam strikes the surface of the tissue substantially at a perpendicular angle thereto.

In accordance with the preferred embodiment, provision is made to protect the skin from overheating due to radiation from pulsed laser beams. A protective substance, such as a cooling substance contained in a cooling apparatus 42, is arranged on the skin, interposed between the skin and the laser beams.

The cooling apparatus 42 is placed on the tissue to cool the tissue that is being exposed to irradiation from a high average power Alexandrite laser beam 44. High average power arises from high energy per pulse and high frequency of the pulse repetition rate. In a preferred embodiment, the cooling apparatus includes a gel 46 of a matching optical index of refraction to that of a operative dyed transparency 48 having died dots 49 thereon and covering gel 46. The gel 46, when spread over the skin, should have a minimum thickness of 2-3 millimeters to be effective in protecting the external surface of the skin for about a 50-100 micron depth against overheating from pulsed laser beams. The gel 46 acts as a heat sink, withdrawing heat accumulating in the external surface of skin from the laser energy.

Fig. 8 illustrates a preferred embodiment of an Alexandrite laser apparatus 100 that comprises an Alexandrite laser source 50 including a conventional Alexandrite laser head 51 and a conventional coupling lens 52, a conventional optical fiber 53 connecting the Alexandrite laser source 50 to a conventional pulsed laser beam director 54 that has an imaging lens 55 and an aperture 56 through which the laser radiation is applied. In the preferred embodiment, apparatus 100 also includes a scanner 57 that causes the laser beam to sweep a pattern on the tissue being irradiated so as to irradiate spots 58 on the tissue. Spots 58 may coincide in registry with marks 49 of the cooling apparatus 42.

Fig. 8 also illustrates a modification of the embodiment of Fig. 4. As in the case of the Fig. 4 embodiment, the tissue 60 is shaved to cut hairs otherwise protruding from the surface of the tissue.

The following parameters are recommended for an Alexandrite laser with a fiber delivery system to remove hair from human beings:

Energy Level:	within 100 mJ-20J/Pulse, optimally 10J/Pulse
Repetition Rate:	10 Pulse per second

	Pulse Duration:	100 microseconds to 3 milliseconds, possibly to 10 milliseconds
	Spot Size on Tissue:	4 - 10 mm.
	Energy Fluence:	15 - 70J/cm ²
5	Tissue Cooling:	4°C.

Based on clinical trials with fifty patients on faces, arms, legs, the acceptable results were observed where the hair diameters ranged between 40 microns to 80 microns. These results are for a single treatment of the arm:

- 30% growth of hairs after 3 months @ 50J/cm²
- 10 50% growth of hairs after 3 months @ 37J/cm²
- 70% growth of hairs after 3 months @ 25J/cm²

In the case of two treatments, in some cases only 15% growth was observed after 3 months. Another effect observed during clinical trials is that for the case of some hair growth, the diameter of the hair is about 25 percent smaller than the original. That is, the treatment causes shrinkage in the hair diameter.

Reference is now made to Figs. 9A and 9B which illustrate an apparatus having a plurality of markings thereon for tracking a laser beam as it sweeps across tissue, e.g., to remove hairs from a patient's skin. The markings indicate whether the laser beam actually reached a location on the skin corresponding to each marking.

Fig. 9A shows a pattern 100 that comprises a plurality of markings 112 which are preferably, but not necessarily, ordered equidistant from each other. The markings 112 may be black dots that vaporize upon impingement of the laser beam thereupon. Fig. 9B shows a pattern 111 that comprises a grid 113 with each grid junction 115 being analogous to the markings 112. Alternatively, the markings 112 or grid junctions 115 may be arranged so that the laser beam will not be directed to impinge them, e.g., may be spaced neighboring the areas to be impinged.

In the embodiments of Figs. 9A and 9B, patterns 110 and 111, respectively, are each on a respective sheet 114 of transparent material. The transparent material may be polyethylene, polypropylene or polycarbonate. The markings 112 and grid 113 are each made of any suitable identifier, such as ink printed on the sheet 114. In a further embodiment of the present invention, patterns 110 and 111 form part of a cooling apparatus as depicted in Figs. 11B and 12. In yet a further embodiment of the present invention, markings 112 are

marked on the skin. In yet another embodiment, the markings are projected on the skin as illustrated with respect to Fig. 13.

5 Figs. 10A - 10C illustrate the progression of the treatment over time with each successive laser pulse directed to a corresponding successive marking 112 so as to vaporize the markings 112 and the associated hairs 124 thereunder by scanning the laser beam across the tissue 60. After pulsing the laser source 50 a desired number of times onto all the markings 112 or grid junctions 115, substantially full coverage of the area to be treated is attained. In an alternative embodiment, the markings 112 or the grid 113 are used to indicate the vicinity and not the exact location on which the laser beam impinges and therefore are not being vaporized by impingement of the laser beam thereupon. The sheet 114 is placed intermediate the laser source 50 and the patient's tissue 60. Preferably, the sheet extends substantially parallel to the skin tissue 60.

Referring now to Fig. 11A, the pattern 110 is illustrated as part of a cooling apparatus 130 so as to further increase the effectiveness of the laser treatment. While the cooling apparatus 130 may be any prior art cooling apparatus, in a preferred embodiment of the present invention, the cooling apparatus 130 comprises a flexible enclosure 132 formed of a relatively thin plastic material, such as polyethylene, polypropylene or polycarbonate, having therein any suitable cooling substance 134. An example of the cooling substance 134 is water, preferably with salt, to decrease its freezing temperature. A transparent sheet 114 with the markings 112 is disposed in enclosure 132 as shown in Fig. 11B. This cooling substance 134 helps protect the skin from thermal damage otherwise arising from pulsed laser beams used in hair removal.

25 A particular feature of the present invention is the use of an ultrasound gel 138, such as the Aquarius 101 Ultrasound gel, commercially available from Meditab Ltd. of Israel. Gel 138 is disposed intermediate the tissue 60 and the cooling apparatus 130. Since enclosure 132 is flexible it is more easy to handle and to place over tissue 60 than a conventional cooling apparatus that is rigid. However, since enclosure 132 need not be necessarily in direct contact with the skin, gel 138 provides the required optical index of refraction matching between the skin and cooling apparatus 130.

According to an alternative preferred embodiment of the present invention illustrated in Fig. 11B, a cooling apparatus 131 is substantially similar to the cooling apparatus 130 and therefore similar elements are referenced in Figs. 11A

and 11B by the same reference numerals. Cooling apparatus 131 differs from cooling apparatus 130 in that it also includes gel 138 enclosed within an enclosure 133 having peelable cover 135. In operation, peelable cover 135 is peeled and cooling apparatus 131 is attached to the skin with attachments 137.

- 5 Preferably, the edge of the enclosure 133 exposed by peeling the peelable cover includes an adhesive material which serves as the attachment 137 for attaching the cooling apparatus to the patient skin.

Cooling apparatus 130 and cooling apparatus 131 are used in conjunction with a laser based skin treatment system, generally referenced 140, illustrated in
10 Fig. 12. Although Fig. 12 is described with respect to cooling apparatus 130, it is equally applicable to cooling apparatus 131.

System 140 includes a laser source 50 operating to provide a pulsed laser beam 44 onto a cooling apparatus 130 and gel 138. In operation, the gel 138 is spread over the area of the skin to be treated and cooling apparatus 130 is placed
15 thereon intermediate gel 138 and laser source 50. A physician (not shown) then operates to treat the skin with the pulsed laser beam 44 as described hereinabove with reference to Figs. 10A through 10C.

While the present invention has been described with respect to markings 112, it is equally applicable to grid junctions 115. Yet another example is to
20 employ a projection apparatus in order to project the markings of the treated area as illustrated in Fig. 13. Fig. 13 shows a light source 150 that projects light through a transparent sheet 152 having markings 154 thereon so as to effectively mark tissue 60 with shade markings 156. Laser 50 operates in the same manner as previously discussed.

25 Fig. 14A shows a cooling apparatus 160 in which the markings are part of the enclosure and not of a transparent marked sheet disposed therein. The cooling apparatus 160 of Fig. 14A comprises an enclosure 161 of which the top part 162 faces away from the skin during operation. The cooling includes discrete marks 163 or a grid thereon and of which the bottom part is a folded removable
30 cover 164. This cover 164 is removed after the cooling apparatus 160 is attached to the skin with attachments 165. Disposed in enclosure 161 is a gel 166 that is used as the cooling agent during operation of the laser on the skin.

In operation, apparatus 160 is placed on the skin and a peelable cover is pulled out by pulling its edge 167. The gel 166 thus comes into contact with the

area to be treated as shown in Fig. 14B and the laser beam is directed onto the treated area bearing the indicia of the plurality of markings 163.

In an alternative embodiment, the peelable cover 164 is removed before the cooling apparatus 160 is tied to the skin.

5 While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be understood that various changes and modifications may be made without departing from the spirit and scope of the present invention. For example, a colored marking at the edge of any cooling apparatus, such as cooling apparatus 160 may be added such that the cooling
10 apparatus marks the area being treated.

For purposes of interpretation of the claims, "markings" covers any form of point indicia, whether ink dots, grid junctions, surface contour indentations or protrusions, etc.

The present invention clearly covers non-invasive hair removal by selective
15 photothermolysis with an Alexandrite laser. However, it also pertains to invasive hair removal with an Alexandrite laser in that a protective substance, such as energy absorbing particles in lotion, fills the hair follicle and effectively blocks laser energy emitting from an invasive laser probe from penetrating to the external layer of the skin. These energy absorbing particles may be carbon black or white
20 reflective that keep the laser energy contained to the hair follicle. In both the invasive and non-invasive techniques, the concept is to pulse the Alexandrite laser and rely on the protective substance to protect the skin against overheating. In this manner, scarring of surrounding tissue from the pulsed laser beam is minimized.

25 While the foregoing description and drawings represent the preferred embodiments of the present invention, it will be understood that various changes and modifications may be made without departing from the spirit and scope of the present invention.

CLAIMS

1. A laser surgery apparatus to remove hair, comprising:
an Alexandrite laser that generates at least one pulsed laser beam that travels in a path and of sufficient energy and pulse duration to damage hair
5 follicle; and
a protective substance arranged in said path to help protect an external surface of the skin against overheating otherwise arising from the pulsed laser beam.
2. An apparatus as in claim 1, further comprising markings that are arranged
10 to provide an indication of where the pulsed laser beam passes through said protective substance, whereby hair follicles that are in the path become damaged by the at least one pulsed laser beam.
3. An apparatus as in claim 1, wherein each of said markings are constructed of a material that vaporizes in response to impingement by the pulsed laser beam.
- 15 4. An apparatus as in claim 1, further comprising a projector that projects the markings onto the protective substance by shining light through a transparent sheet having markings.
5. An apparatus as in claim 1, wherein said markings are responsive to impingement by the pulsed laser beam to provide the indication.
- 20 6. An apparatus as in claim 1, wherein said pulsed laser beam has a pulse duration of 100 microseconds to 10 milliseconds.
7. An apparatus as in claim 1, wherein said Alexandrite laser generates a plurality of pulsed laser beams, further comprising a scanner that directs said pulsed laser beams to sweep across said protective substance in a vicinity of said
25 markings in accordance with a pattern.
8. An apparatus as in claim 1, further comprising an enclosure containing said protective substance, said enclosure being interposed in said path.
9. An apparatus as in claim 8, wherein said enclosure includes a plurality of sheets of transparent material.
- 30 10. An apparatus as in claim 9, wherein said sheets of constructed of a plastic material selected from the group consisting of polyethylene, polypropylene, polycarbonate, and any combination thereof.
11. An apparatus as in claim 8, further comprising an ultrasound gel within said enclosure.

12. An apparatus as in claim 8, further comprising an ultrasound gel in contact with an exterior of said enclosure.
13. An apparatus as in claim 8, wherein said enclosure is flexible.
14. An apparatus as in claim 1, wherein said markings are selected from the group consisting of inks, light projections, and configurations in said envelope.
15. An apparatus as in claim 1, wherein said protective substance is an ultrasound gel.
16. An apparatus as in claim 1, wherein any one of stain and stained lotion is in said path such that said protective substance is between said Alexandrite laser and said any one of said stain and stained lotion.
17. An apparatus as in claim 1, wherein said Alexandrite laser emits energy between 0.2-40 joules per pulse.
18. An apparatus as in claim 1, wherein said Alexandrite laser emits pulsed laser beams with a pulse repetition rate of 1 pulse per second to 15 pulses per second.
19. An apparatus as in claim 1, wherein said Alexandrite laser provides an energy fluence of between 15 joules per centimeter squared and 70 joules per centimeter squared.
20. An apparatus as in claim 1, wherein said Alexandrite laser provides said pulsed laser beam such that said pulse duration is shorter than a thermal relaxation time of the hair follicle.
21. A method of laser surgery to remove hair, comprising:
generating at least one pulsed laser beam that travels in a path from an Alexandrite laser and of sufficient energy and pulse duration to damage hair follicle; and
interposing a protective substance in the path to help protect an external surface of the skin against overheating otherwise arising from the pulsed laser beam.
22. A method as in claim 21, further comprising the step of indicating with markings where the pulsed laser beam passes through the protective substance, whereby hair follicles that are in the path become damaged by the at least one pulsed laser beam.
23. A method as in claim 22, wherein said markings vaporize in response to the pulsed laser beam impinging said markings.

24. A method as in claim 22, further comprising the step of indicating includes projecting the markings by shining light at the protective substance through a transparent sheet with markings.
25. A method as in claim 22, wherein the step of indicating arises in response
5 to the pulsed laser beam impinging the markings.
26. A method as in claim 22, wherein said Alexandrite laser generates a plurality of pulsed laser beams, further comprising scanning with the pulsed laser beams to sweep across the cooling substance in a vicinity of the markings in accordance with a pattern.
- 10 27. A method as in claim 21, further comprising enclosing the protective substance within an enclosure, the enclosure being transparent.
28. A method as in claim 21, further comprising contacting the envelope with an ultrasound gel.
29. A method as in claim 21, further comprising flexing said enclosure.
- 15 30. A method as in claim 21, further comprising staining hair and arranging the path so that the pulsed laser beam strikes the stained hair.
31. A method as in claim 21, wherein the Alexandrite laser emits energy between 0.2-70 joules per pulse.
32. A method as in claim 21, wherein the Alexandrite laser generates pulsed
20 laser beams that have a pulse repetition rate of 1 pulse per second to 15 pulses per second.
33. A method as in claim 21, wherein said Alexandrite laser provides energy fluence of between 15 joules per centimeter squared and 40 joules per centimeter squared.
- 25 34. A method as in claim 21, further comprising the step of shaving hairs and then directing the path of the pulsed laser beam to strike the shaved hairs.
35. A method as in claim 21, further comprising the step of keeping the path away from the markings at all times.
36. A method as in claim 21, wherein the step of generating includes
30 generating the pulsed laser beam such that the pulse duration that is shorter than a thermal relaxation time of melanin.
37. A method as in claim 21, wherein the step of generating causes the pulsed laser beam to have a pulse duration between 10 microseconds and 10 milliseconds.

38. A method of hair removal, comprising the step of applying at least one Alexandrite laser pulse to at least one hair follicle, said Alexandrite laser pulse having sufficient pulse duration and radiant exposure dose of sufficient energy to damage said at least one hair follicle so that percentage hair growth diminishes and scarring of the surrounding skin is minimized.

39. A method as in claim 34, wherein said pulse duration is between 10 microseconds and 10 milliseconds.

40. A method as in claim 39 wherein said step of applying comprising the steps of:

aligning a laser light applicator over said at least one hair follicle opening in tissue, said applicator having an aperture of sufficient area to surround said at least one hair follicle and overlie its papilla; and

directing through said aperture to said at least one hair follicle said at least one pulse of laser radiation.

41. A method as in claim 38, further comprising the step of absorbing part of said at least one laser pulse with stain that has been added to the one hair follicle.

42. A method as in claim 38, wherein said Alexandrite laser emits energy between 2-70 joules per pulse.

43. A method as in claim 38, wherein said Alexandrite laser emits energy at a pulse repetition rate of 1 pulse per second to 15 pulses per second.

44. A method as in claim 38, wherein said directing comprises directing the laser beam through a scanner to deliver the laser radiation to tissue in a homogenous manner.

45. A method as in claim 38, wherein said Alexandrite laser provides an energy fluence of between 15 joules per centimeter squared and 40 joules per centimeter squared to said at least one hair follicle.

46. A method as in claim 38, wherein each said Alexandrite laser pulse is arranged to irradiate spots on the tissue with the Alexandrite laser, each of the spots having a spot size on the tissue between 3-8 millimeters.

47. A method as in claim 38, wherein the step of applying provides an energy fluence on the tissue that results in a percentage growth of hairs after 3 months that is in accordance with a relationship between percentage growth after 3 months and energy fluence, the relationship being characterized by a curve profile whose coordinates include:

30% growth of hairs after 3 months @ 50J/cm²

50% growth of hair after 3 months @ 37J/cm²

70% growth of hairs after 3 months @ 25J/cm².

48. A method as in claim 38, wherein the step of applying is such that the pulse duration is shorter than a thermal relaxation time of the melanin.

5 49. A method as in claim 38, further comprising the step of shaving the hair follicle before the step of applying so that the hair follicle is free from protruding from the skin to a position that would scatter radiant energy from the laser pulse upon infringement.

10 50. An apparatus for hair removal, comprising:

- 15 a. an Alexandrite laser source for generating at least one alexandrite laser pulse having a sufficient pulse duration and radiant exposure dose of sufficient energy to damage at least one hair follicle so that percentage hair growth diminishes and scarring of the surrounding skin is minimized; and
- 20 b. a laser light applicator that directs said laser pulses to said at least one hair follicle.

51. An apparatus as in claim 50, wherein said pulse duration is between 100 microseconds and 10 milliseconds.

25 52. An apparatus as in claim 50 wherein said laser light applicator is aligned over said at least one hair follicle opening in tissue, said applicator having an aperture of sufficient area to surround said at least one hair follicle and overlie its papilla so that said at least one pulse of laser radiation is directed through said aperture to said at least one hair follicle.

30 53. An apparatus as in claim 50, further comprising stain arranged so that said stain absorbs at least part of said at least one laser pulse.

54. An apparatus as in claim 50, wherein said Alexandrite laser emits energy between 0.2-40 joules per pulse.

55. An apparatus as in claim 50, wherein said Alexandrite laser emits energy at a pulse repetition rate of 1 pulse per second to 15 pulses per second.

56. An apparatus as in claim 50, further comprising a scanner operative to deliver the laser radiation via said laser light applicator to tissue in a homogenous manner.

57. An apparatus as in claim 50, wherein said Alexandrite laser provides an energy fluence of between 15 joules per centimeter squared and 70 joules per centimeter squared to said at least one hair follicle.

58. An apparatus as in claim 50, wherein each said laser light application is arranged to direct said laser pulses to irradiate spots on the tissue so that each of the spots has a spot size on the tissue between 3-8 millimeters.

59. An apparatus as in claim 50, wherein said laser source provides a level of energy fluence on the tissue that results in a percentage growth of hairs after 3 months that is in accordance with a relationship between percentage hair growth after 3 months and energy fluence, the relationship being characterized by a curve profile whose coordinates include:

30% growth of hairs after 3 months @ 50 J/cm²
50% growth of hairs after 3 months @ 37J/cm²
70% growth of hairs after 3 months @ 25J/cm².

60. An apparatus as in claim 50, wherein said Alexandrite laser source provides the alexandrite laser pulse such that the pulse duration is shorter than a thermal relaxation time of melanin.

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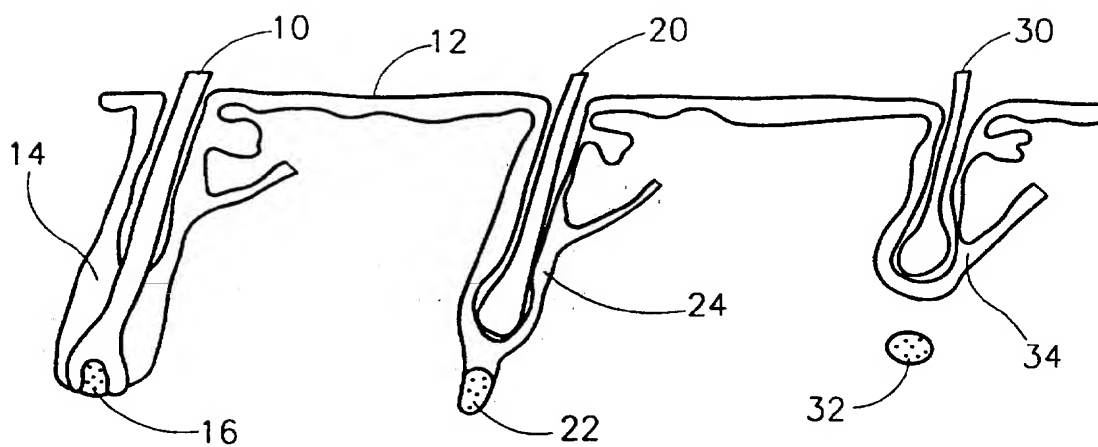


FIG. 1

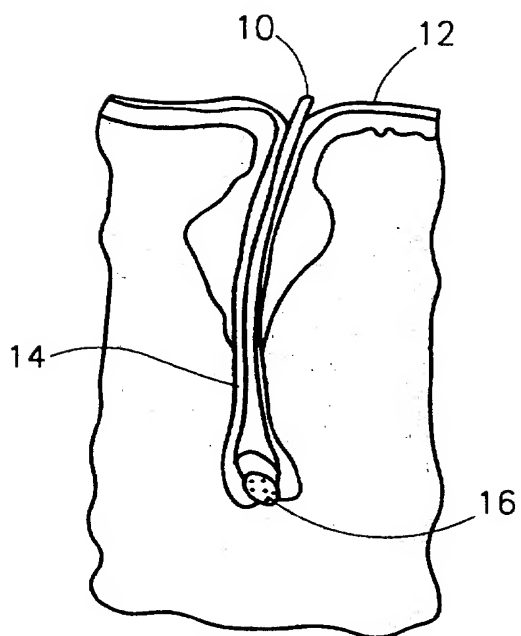


FIG. 2

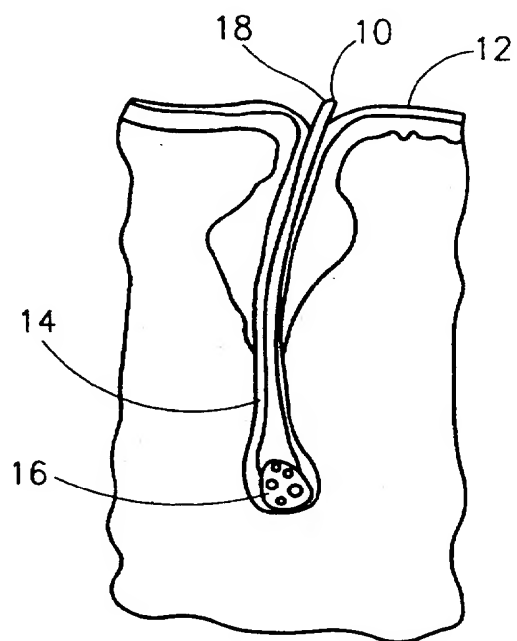


FIG. 3

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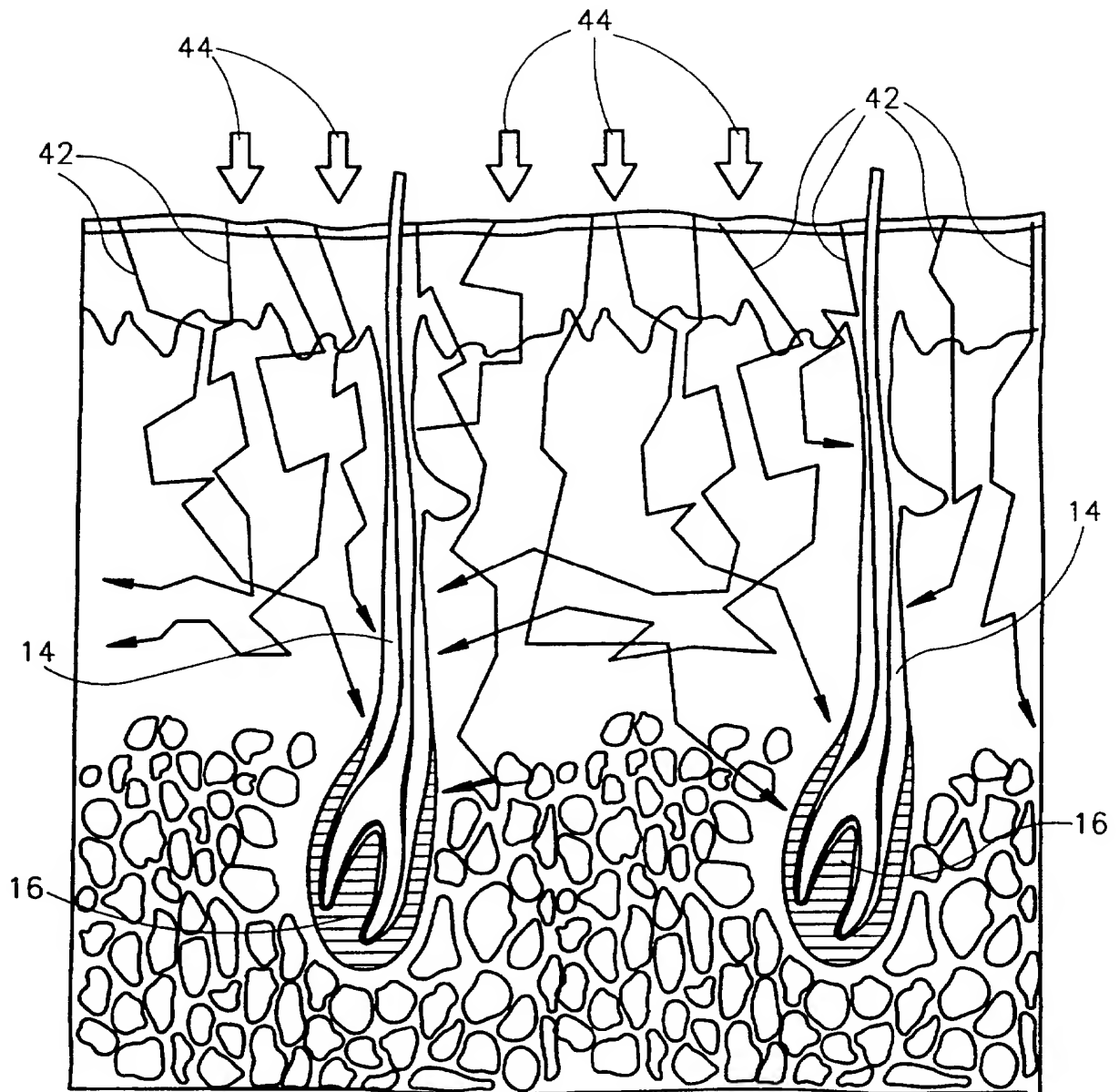


FIG.4

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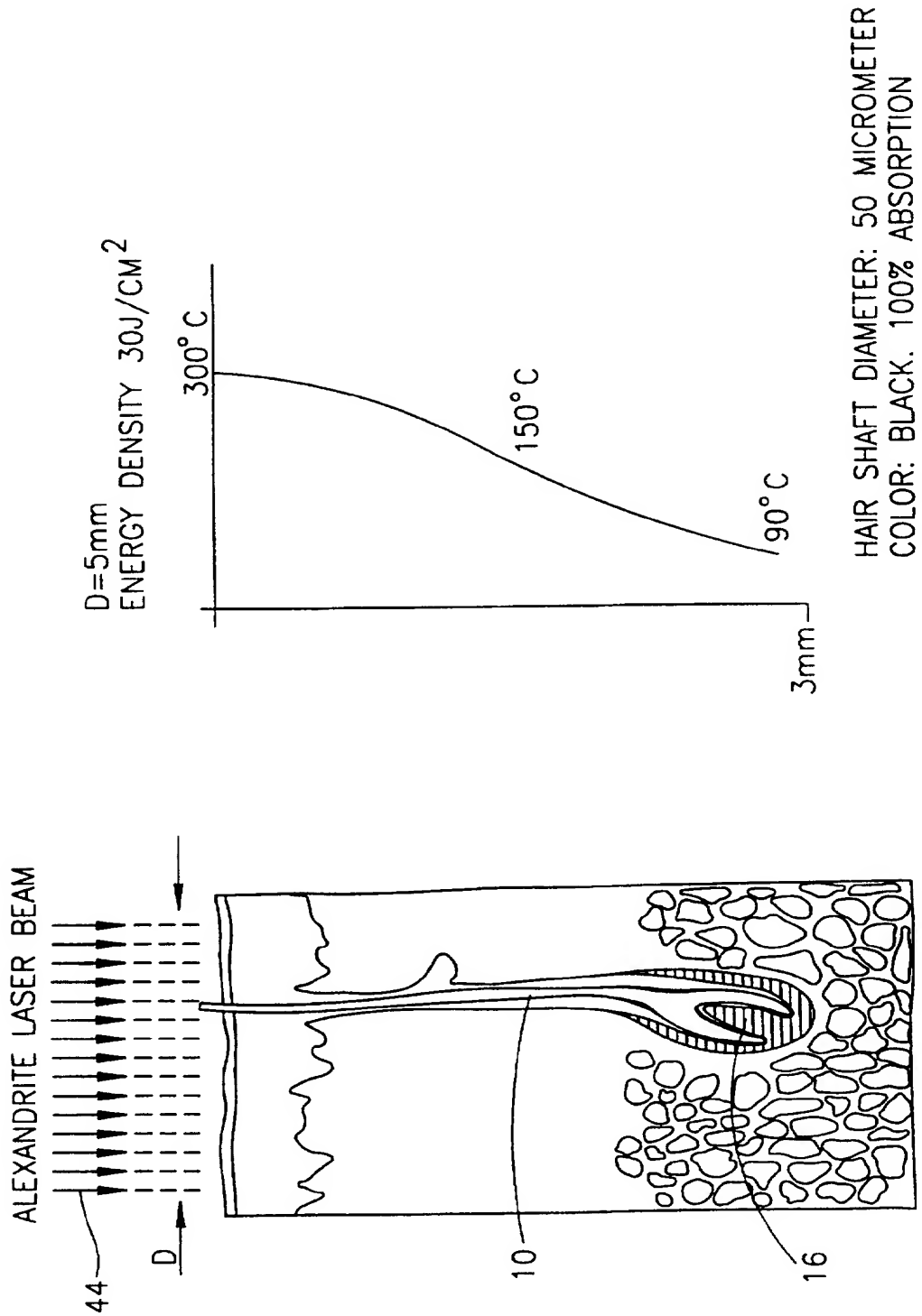


FIG. 5B

FIG. 5A

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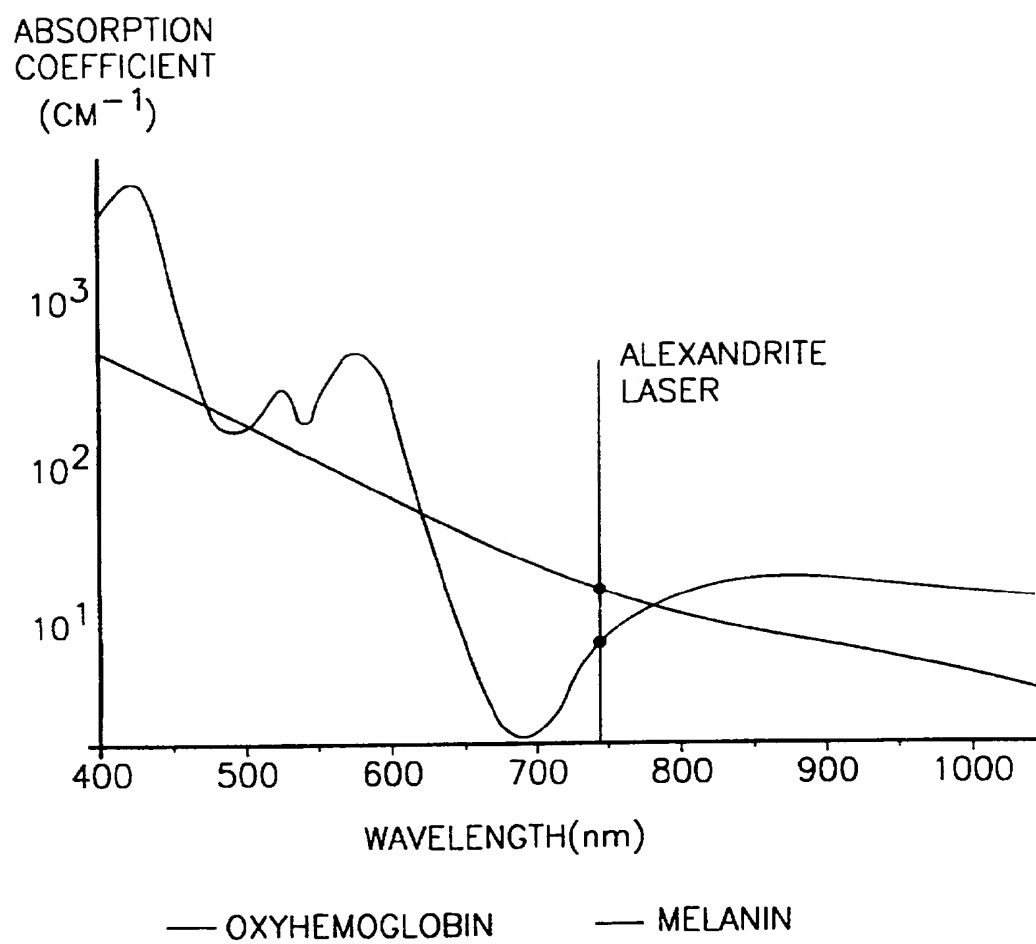


FIG.6

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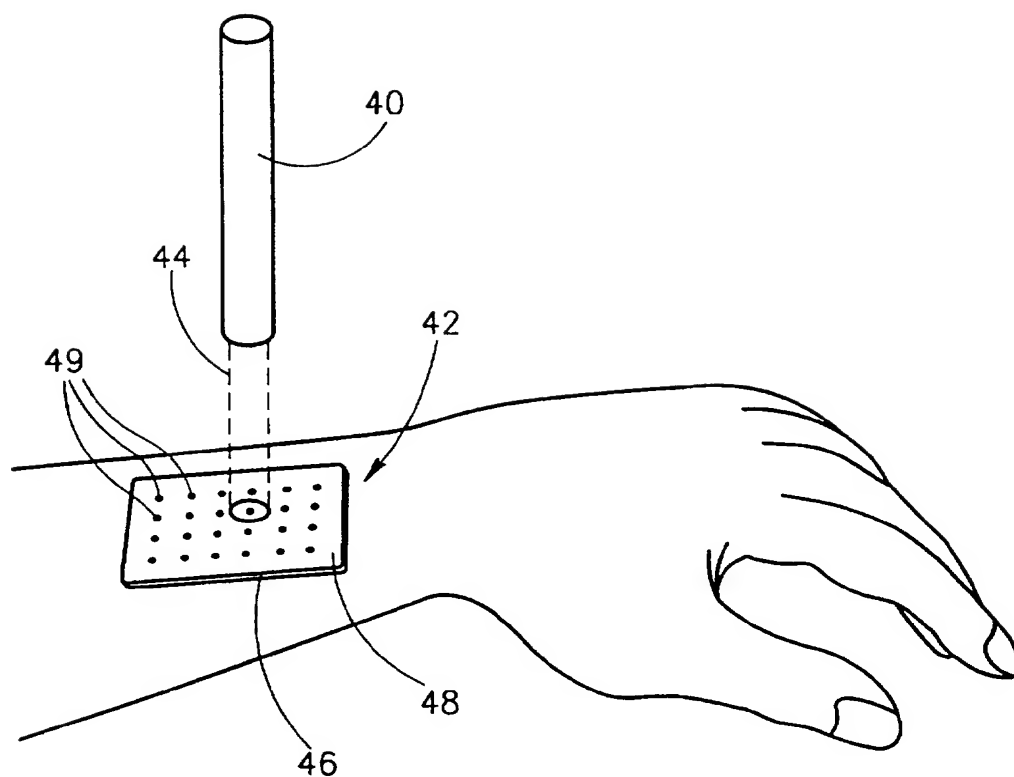


FIG. 7

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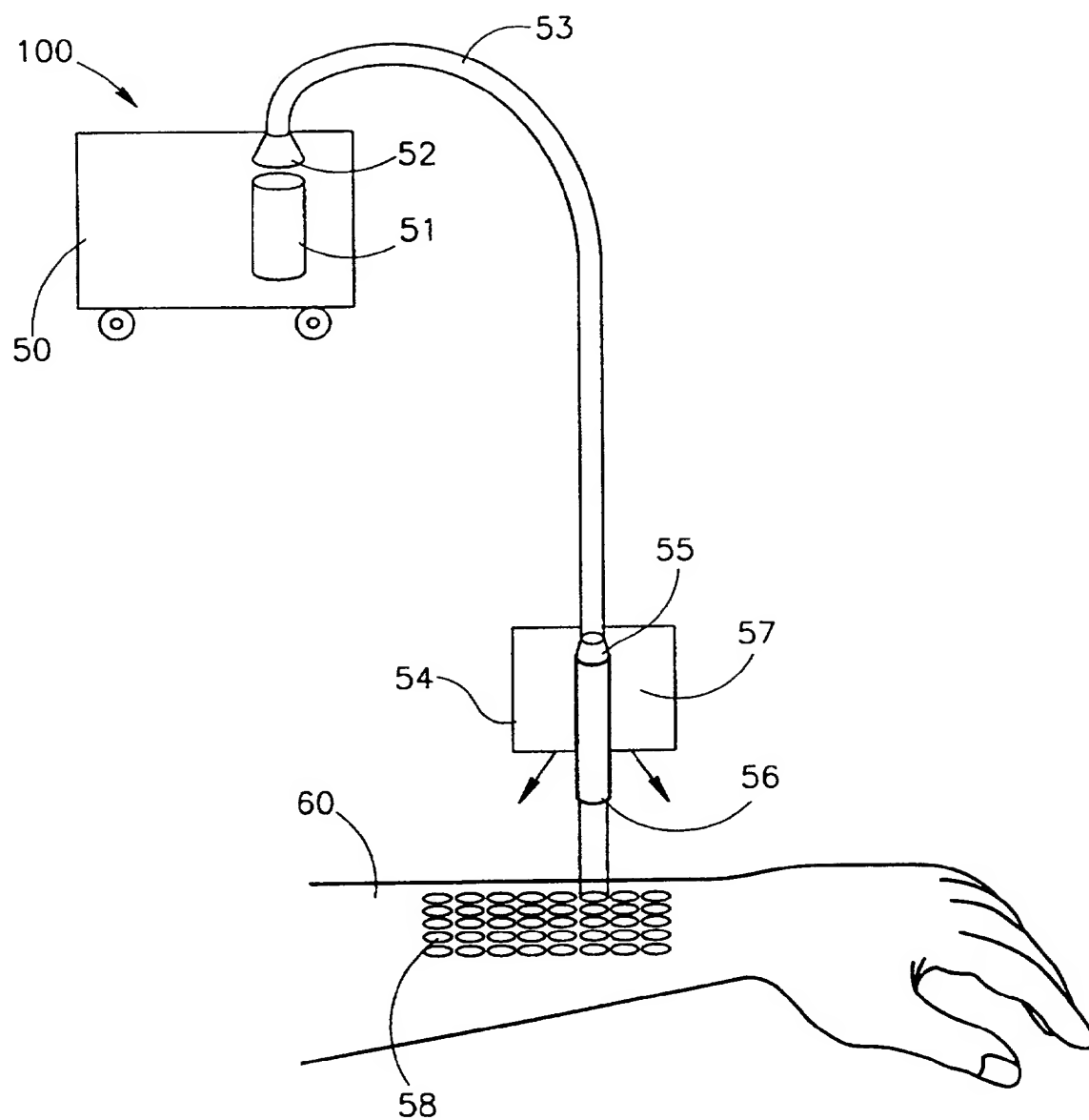
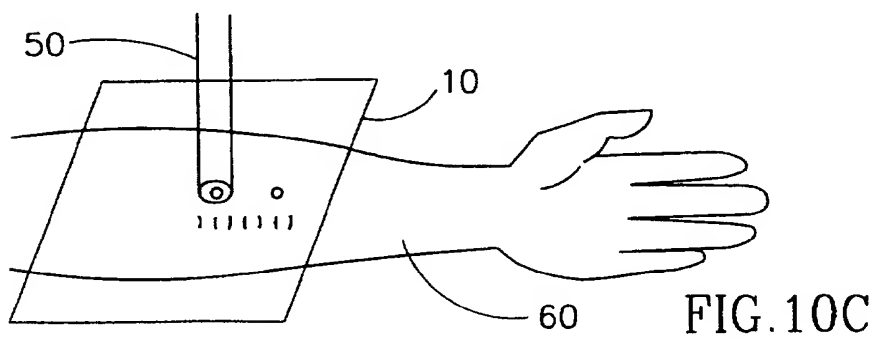
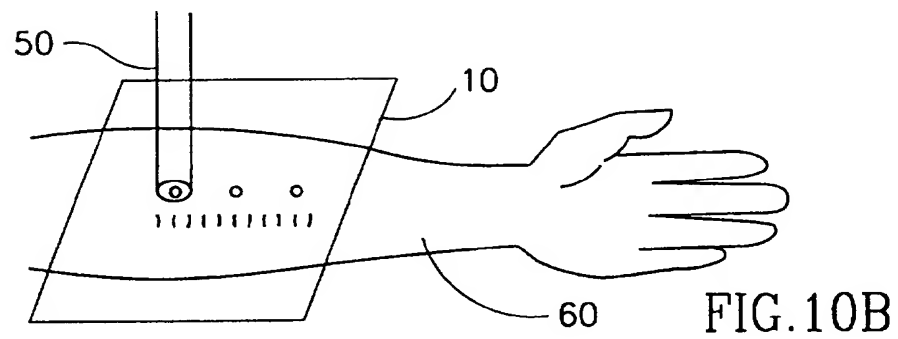
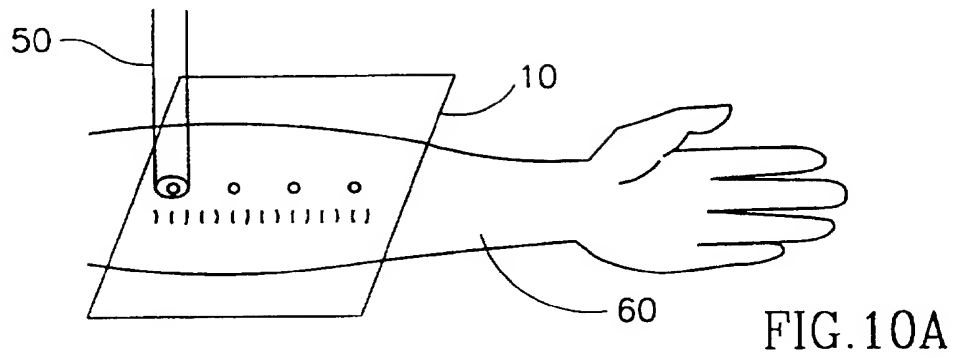
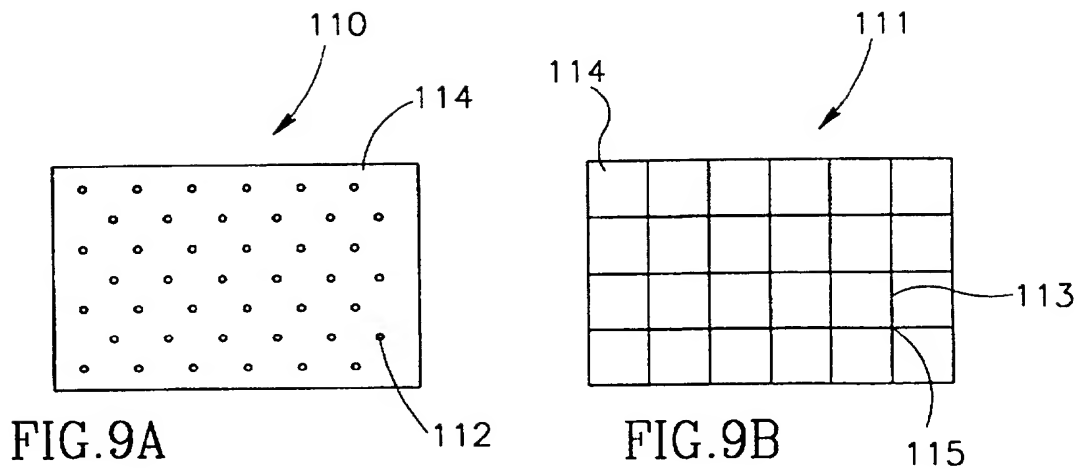


FIG. 8

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8/10

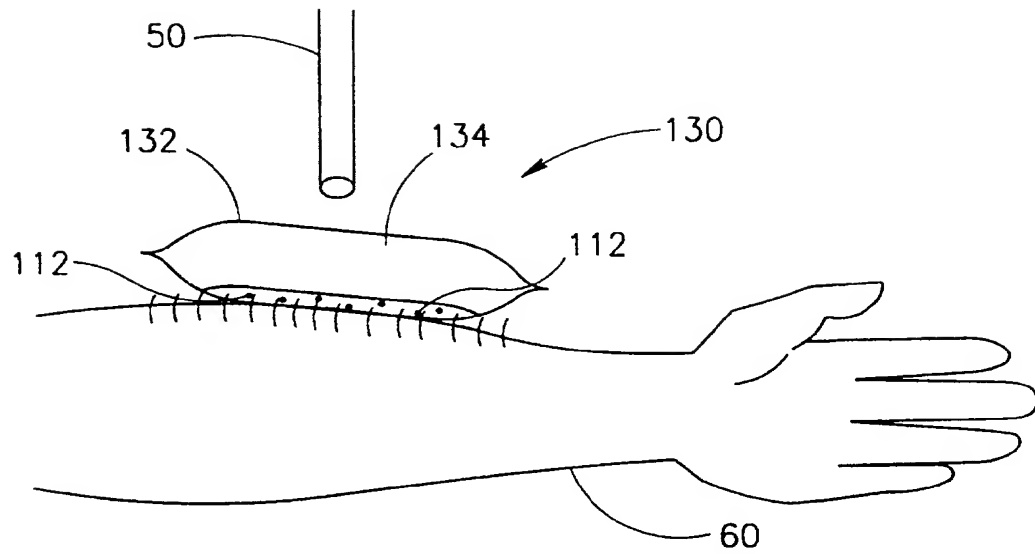


FIG. 11A

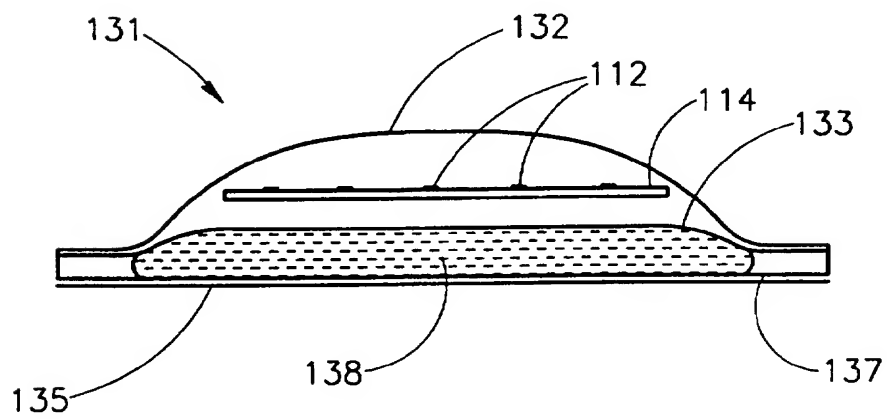


FIG. 11B

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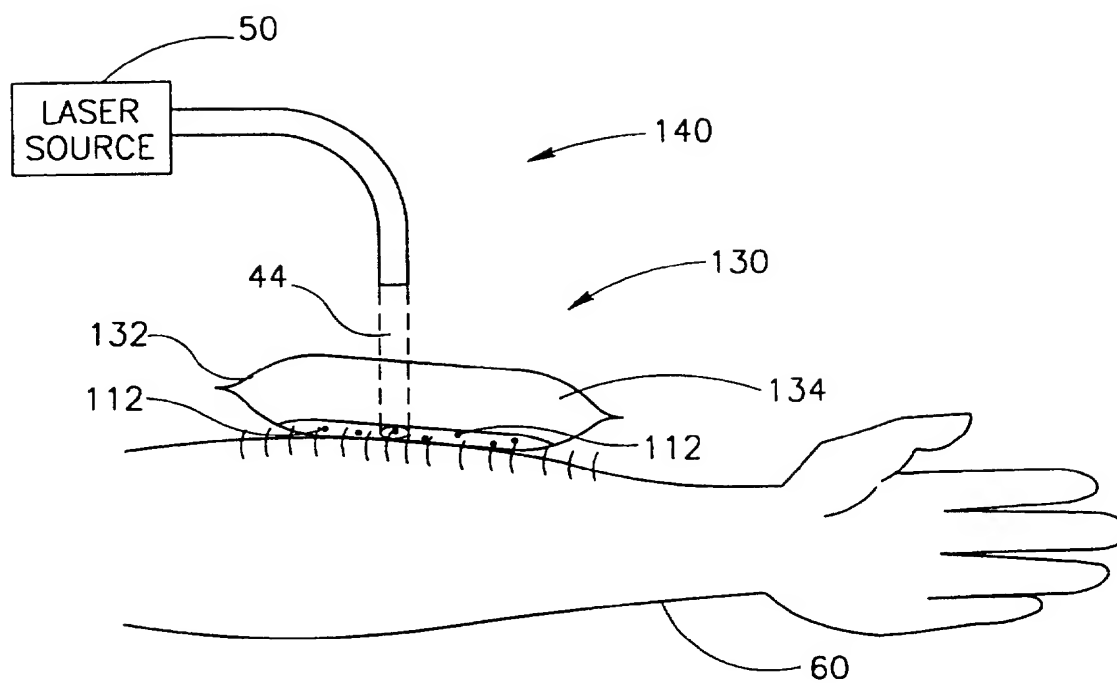


FIG. 12

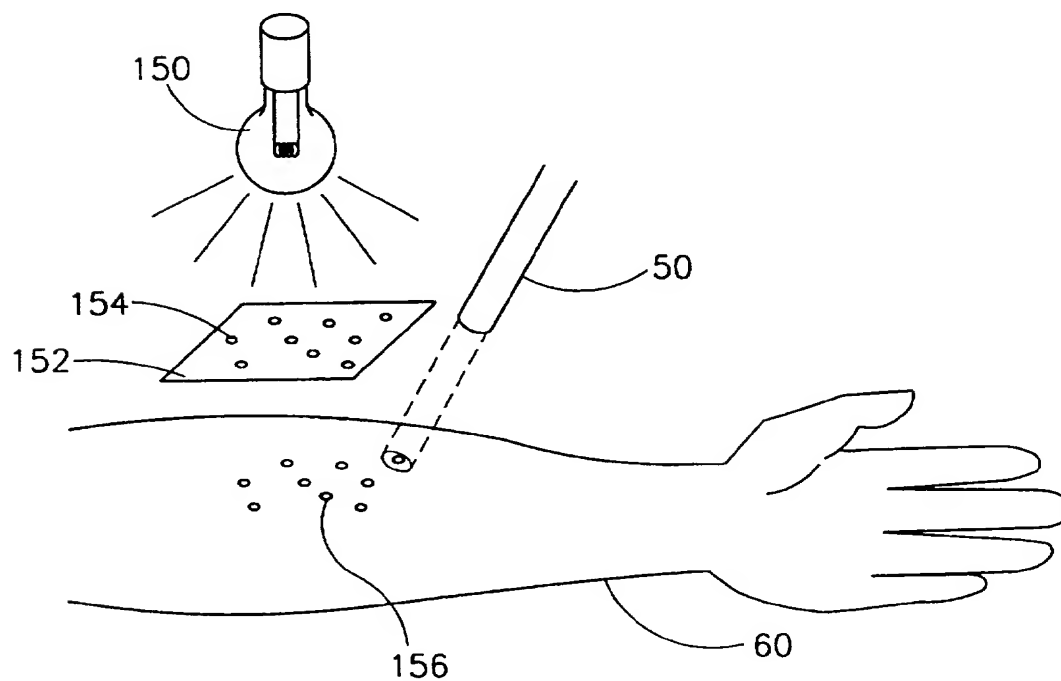
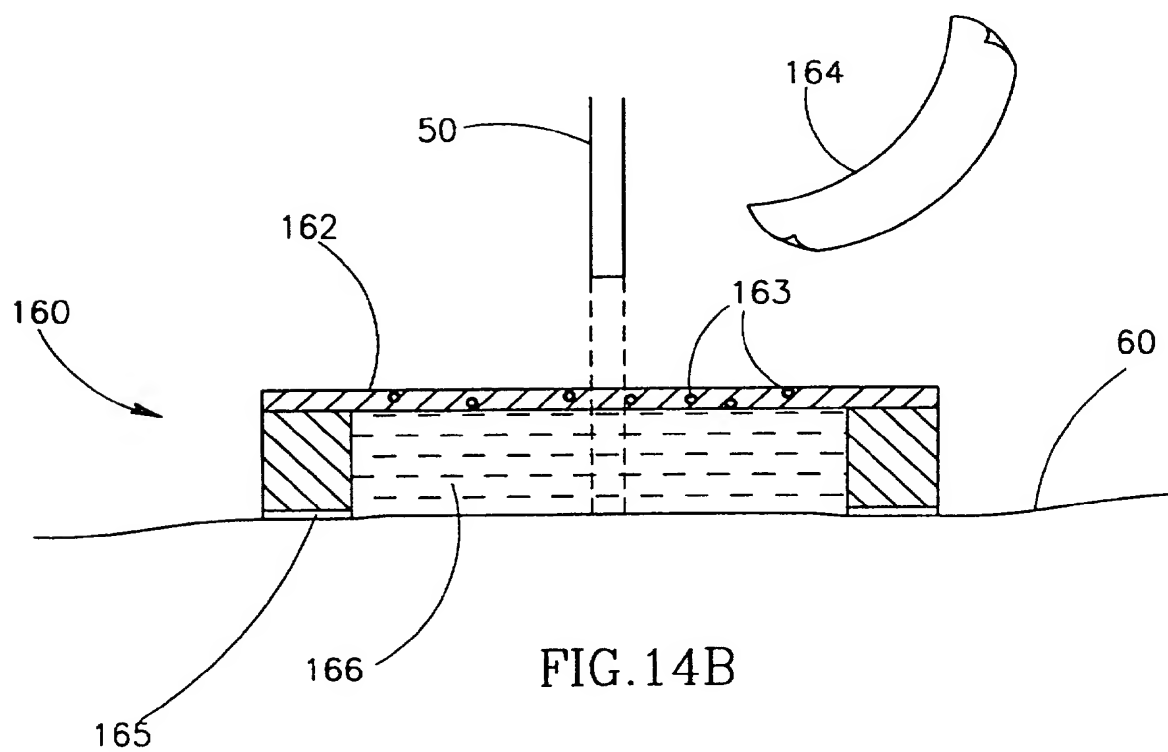
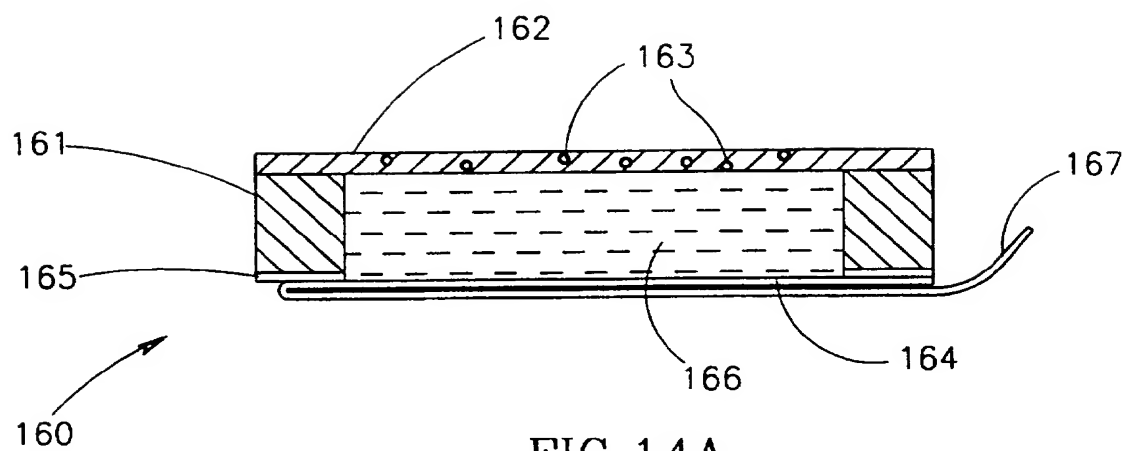


FIG. 13

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INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/IL96/00184

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61N 5/06

US CL : 606/9

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/9-17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 91/13652 A (FURUMOTO et al) 19 September 1991, entire document.	1-3, 6, 7, 17-21, 26, 31-34, 36-39, 42-60
Y	US 5,282,797 A (CHESS) 01 February 1994, entire document.	1-5, 8, 21, 27
Y	US 4,617,926 A (SUTTON) 21 October 1986, entire document.	40, 50
Y	US 5,486,172 A (CHESS) 23 January 1996, entire document.	1-60

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents.	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

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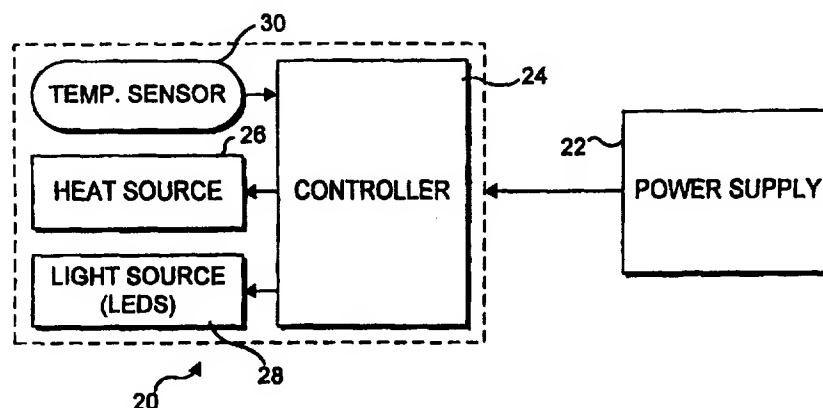
SONYA HARRIS-OGUGUA

Telephone No. (703) 308-2216

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61N 1/30	A1	(11) International Publication Number: WO 98/04317 (43) International Publication Date: 5 February 1998 (05.02.98)
(21) International Application Number: PCT/US97/11050 (22) International Filing Date: 26 June 1997 (26.06.97) (30) Priority Data: 08/688,058 29 July 1996 (29.07.96) US (71) Applicant: LIGHT SCIENCES LIMITED PARTNERSHIP [US/US]; 1065 - 12th Avenue N.W. #E5, Issaquah, WA 98027 (US). (72) Inventors: CHEN, James, C.; 2011 - 87th Place N.E., Bellevue, WA 98004 (US). WISCOMBE, Brent; 3014 East Holmes, Mesa, AZ 85204 (US). (74) Agent: ANDERSON, Ronald, M.; Law Offices of Ronald M. Anderson, Suite 1710, 500-108th Avenue N.E., Bellevue, WA 98004 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>With amended claims.</i>

(54) Title: METHOD AND DEVICE FOR APPLYING HYPERTHERMIA TO ENHANCE DRUG PERFUSION AND EFFICACY OF SUBSEQUENT LIGHT THERAPY

**(57) Abstract**

A method and apparatus for applying heat to a treatment site prior to effecting photodynamic therapy. The perfusion of a drug into abnormal tissue in a tumor (12) is enhanced by heating the treatment site at which the tumor is disposed using a heat source (26) mounted on a fixture (20, 34) separate from a light source (28) on a probe used to effect the photodynamic therapy. Alternatively, the heat source and light source may comprise different types of light emitting diodes (LEDs) arranged in an array on a probe (14) disposed at the treatment site. Also mounted on the fixture is a temperature sensor (30), which produces a signal indicative of the temperature at the treatment sensor (30), which produces a signal indicative of the temperature at the treatment site. In response to this signal, a controller (24/36) controls the heat source to prevent vascular damage. In addition to enhancing the perfusion of a photoreactive agent into the treatment site, heating the tissue at the site prior to initiating the PDT greatly enhances the efficacy of this treatment.

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METHOD AND DEVICE FOR APPLYING HYPERTHERMIA TO ENHANCE DRUG PERFUSION AND EFFICACY OF SUBSEQUENT LIGHT THERAPY

Field of the Invention

5 The present invention generally relates to a device and a procedure for applying heat to tissue, and more specifically, to the use of this device and procedure for enhancing the effects of a medical treatment that depends upon the perfusion of a reagent into the tissue.

Background of the Invention

10 Abnormal tissue in the body is known to selectively absorb certain dyes perfused into a treatment site to a much greater extent than surrounding tissue. For example, tumors of the pancreas and colon may absorb two to three times the volume of certain dyes, compared to normal tissue. Once pre-sensitized by dye tagging, the cancerous or abnormal tissue can be destroyed by irradiation with
15 light of an appropriate wavelength or waveband corresponding to an absorbing wavelength or waveband of the dye, with minimal damage to normal tissue. This procedure, which is known as photodynamic therapy (PDT), has been clinically used to treat metastatic breast cancer, bladder cancer, lung carcinomas, esophageal cancer, basal cell carcinoma, malignant melanoma, ocular tumors, head and neck
20 cancers, and other types of malignant tumors. Because PDT may selectively destroy abnormal tissue that have absorbed more of the dye than normal tissue, it can successfully be used to kill malignant tissue with less effect on surrounding benign tissue than alternative treatment procedures.

 Typically, invasive applications of PDT are used during surgical
25 procedures employed to gain access to a treatment site inside the body of the patient to administer light produced by relatively high intensity light sources, such as high power lasers or solid state laser diode (LD) arrays. Optical fibers in a hand-held probe are often used to deliver the intense light to the surgically

exposed treatment site from a remote laser source to reduce damage to surrounding tissue from the heat developed by the laser source.

It has been shown possible, in certain cases, to obtain improved therapeutic results in PDT at a low light level. As reported by J. A. Parrish in
5 "Photobiologic Consideration in Photoradiation Therapy," pp. 91-108, Porphyrin Photosensitization, Plenum Press, (1983), preliminary laboratory studies with hematoporphyrin and visible light suggest that low intensity light may be more effective in PDT. In these experiments, subcutaneous tumors in the flanks of
10 newborn rats were treated with the same external dose of 620 nm radiation, at intensities of 7.5, 28, and 75 mW/cm². At the same total light dosage, Parrish found that greater tumor necrosis occurred at the lowest light intensity used.

Light emitting probes designed to be transcutaneously introduced into the body of a patient at a desired treatment site, to administer PDT using low light level sources, for extended periods of time, are taught in commonly assigned U.S.
15 Patent No. 5,445,608, the drawings and disclosure of which are specifically incorporated herein by reference. Several different embodiments of such probes are illustrated and discussed in this patent. Each of the probes disclosed in this reference includes a plurality of light sources that are mounted on a substrate and enclosed within a transparent envelope through which light emitted by the light
20 sources is transmitted to the tumor or other cells to be destroyed by PDT. The light sources used on the probes taught by this reference are preferably light emitting diodes (LEDs). By transcutaneously inserting one of these probes into an internal treatment site and applying PDT over an extended time frame, abnormal tissue at the treatment site can be destroyed without adverse impact on normal
25 tissue.

U.S. Patent No. 5,445,608 discloses that a light source on a probe implanted at a treatment site within a patient's body will give off heat that increases the temperature of the abnormal tissue at the treatment site. An increase in the efficacy of PDT is thus achieved due to the elevated temperature of the
30 tissue. Other beneficial effects of hyperthermia are known in the prior art. For example, hyperthermia has been utilized to enhance permeation of various medicaments into the tissue comprising a tumor. It is believed that an increase in blood flow in the tissue subject to hyperthermia and/or an enlargement of endothelial gaps within the tumor vessels may be responsible for enhanced drug
35 delivery to a tumor site. Another beneficial use of hyperthermia applied to a

tumor site is to split heat sensitive liposomes containing antitumor agents, and thus, to provide selective drug delivery to the site.

Abnormal tissue in a tumor differs from normal tissue in its resistance to the perfusion of medicaments. In addition, as any treatment of a tumor begins to
5 destroy cells on the surface of the tumor, the necrotic cell layer resulting from the treatment tends to resist infusion of medicaments to the underlying live abnormal tissue. It would thus be desirable to enhance the perfusion of medicament fluids such as photoreactive reagents into the tissue of the tumor that will subsequently be destroyed by PDT. Further, it would be desirable to enhance the efficiency of
10 PDT without the need for additional hardware to be inserted into the treatment site beyond that necessary to administer PDT. The present invention addresses these objectives.

Summary of the Invention

In accord with the present invention, a method for increasing the perfusion
15 of a drug through tissue at a treatment site where photodynamic therapy is to be administered comprises the step of positioning a fixture that emits light adjacent to the treatment site for use in administering the photodynamic therapy. The fixture includes means for providing heat to the tissue at the treatment site to raise its temperature. The drug is then delivered to the treatment site. The elevated
20 temperature of the tissue caused by the heat that was supplied increases the perfusion of the drug through the tissue at the treatment site to enhance the effect of the drug on the tissue.

In the preferred embodiment of the invention, the drug comprises a photoreactive reagent. A light source provided on the fixture is used to irradiate
25 the tissue at the treatment site after the perfusion of the photoreactive agent through the tissue has been enhanced by heating the tissue, to administer the photodynamic therapy.

The fixture preferably includes a first light source that emits light having a first waveband, which substantially overlaps a characteristic absorption waveband
30 of the drug delivered to the tissue at the treatment site and which is energized to administer the photodynamic therapy. A second light source on the fixture emits light having a second waveband substantially different from the first waveband. The second light source comprises the means for heating, where the second waveband of the light emitted by the second light source heats the tissue, but
35 generally are not used to implement PDT. The first and second light sources preferably comprise an array of light emitting solid state devices.

Another step of the method provides for monitoring a temperature of the tissue at the treatment site, producing a signal indicative of the temperature. The means for providing heat are then controlled in response to the signal indicative of the temperature of the tissue at the treatment site, so that the temperature does not
5 exceed a level likely to cause vascular damage.

In one preferred embodiment, the treatment site is internal to a patient's body, and the fixture is disposed at the internal treatment site to provide heat and to administer the photodynamic therapy. The fixture of this embodiment comprises a probe that is adapted to be left within the patient's body for an
10 extended period of time while PDT is administered. In another use of the present invention, the drug that infuses throughout the heated tissue is employed for a medical treatment other than PDT.

Instead of using a light source to produce heating of the treatment site, a resistive element can be employed to generate heat. The resistive element can be
15 coupled to a power source using conductors that are separate from those supplying power to the light source used for PDT so that the light source and resistive element can be separately controlled.

An alternative embodiment uses a light source for both PDT and as the means for heating the treatment site. In this embodiment of the invention, the
20 light source can be activated prior to administration of the drug, to heat the treatment site, and then de-energized. After the drug is administered, the light source is again activated to provide the light required for PDT.

In addition to enhancing the perfusion of the drug in tissue at the treatment site, heat applied to the treatment site can be used to release the drug from a drug
25 carrier. Heat sensitive drug carriers such as liposomes and polymers are usable for this purpose.

Another aspect of the present invention is directed to an apparatus for increasing a perfusion of a drug through tissue at a treatment site where PDT is to be administered. The apparatus generally includes components that implement
30 functions consistent with the steps and other details of the method described above.

Brief Description of the Drawing Figures

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same becomes better
35 understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1 is a schematic view showing a tumor, a PDT probe, and a portion of a syringe that is being used to inject a drug into the tumor;

FIGURE 2 is a schematic block diagram of a first embodiment of the present invention, showing an implantable fixture having a separate heat source and light source for respectively applying heat and PDT to an internal treatment site, a controller, and a temperature sensor for monitoring the temperature of tissue at the treatment site;

FIGURE 3 is a schematic block diagram of a second embodiment of the present invention, which is similar to that of FIGURE 2, except that the heat source and light source comprise an array of LEDs;

FIGURE 4 is a schematic block diagram of a third embodiment of the present invention, which is similar to the first, except that the controller is separate from the fixture;

FIGURE 5 is a schematic block diagram of a fourth embodiment of the present invention, which is similar to the second embodiment, except that the controller is separate from the fixture;

FIGURE 6 is a schematic block diagram of a data transmitter and receiver for transmitting a temperature signal to an external monitor;

FIGURE 6A is a schematic block diagram of the controller;

FIGURE 7 is a schematic diagram of a thermocouple used for a temperature sensor to monitor the temperature of tissue at the treatment site; and

FIGURE 8 is a schematic block diagram showing a portion of an implantable probe in accord with the present invention.

Description of the Preferred Embodiments

A treatment site 10 within a patient's body (not otherwise shown) is schematically illustrated in FIGURE 1. At treatment site 10, a tumor 12 comprising cancerous or other abnormal tissue having a generally amorphous shape is illustrated by a dashed line. The present invention is intended for applying medical treatment to tumor 12 with the expectation that the abnormal tissue will be killed thereby, eliminating the tumor or at least substantially reducing its size. As explained above in the Background of the Invention, and in much greater detail in U.S. Patent No. 5,445,608, which has been incorporated herein, a PDT probe 14 can be implanted within a patient's body at treatment site 10 to deliver PDT for an extended period of time. PDT probe 14 includes a plurality of solid state light sources, such as light emitting diodes (LEDs), laser diodes, electroluminescent devices, resistive filament lamps, or vertical cavity

surface emitting lasers (VCSELs), which are not separately shown in FIGURE 1. To effect PDT, a photoreactive agent is infused into the abnormal tissue comprising tumor 12. Since the photoreactive agent is preferentially absorbed by the abnormal tissue rather than by the surrounding normal tissue, the effect of PDT on the abnormal tissue of the tumor is substantially more pronounced than its effect on the surrounding normal tissue.

In FIGURE 1, a syringe 16 coupled to a needle 18 is illustrated in a position for infusing the photoreactive agent into tumor 12. It is also contemplated that the photoreactive agent can be delivered to tumor 12 in other ways, such as by a general infusion of the reagent into a patient's vascular system, orally, or by delivery through a lumen of a catheter coupled to PDT probe 14; the electrical leads attached to probe 14 are generally represented by a line 15 in FIGURE 1. Alternatively, a heat sensitive drug carrier such as a liposome or a polymer can carry the drug to the treatment site so that when the treatment site is heated by the PDT probe, the drug carrier releases the drug into the treatment site so that the drug infuses throughout the tissue at the site.

In connection with the present invention, PDT probe 14 comprises a fixture, such as fixture 20 as shown in FIGURE 2. This fixture may have several different configurations or embodiments, others of which are illustrated in FIGURES 3-5. In the first embodiment shown in FIGURE 2, fixture 20 is coupled to a power supply 22. Power supply 22 may comprise a battery source, which is disposed within the patient's body, either at the same site as the PDT probe, or at a different location. Alternatively, power supply 22 may be disposed externally, and coupled through leads 15 to the PDT probe. It is also contemplated that if disposed internally, electrical power may be transferred from outside the patient's body to the power supply using a source of infrared light that passes readily through the dermal layer of a patient's body. The infrared light is thus received by a photovoltaic transducer (not shown) disposed within the patient's body. Alternatively, power may be supplied from an external source using an electromagnetic field. In this approach, an external coiled conductor, which is energized from an alternating current (AC) or pulsating direct current (DC) source can electromagnetically couple power to a conductor coil disposed within the patient's body. The power thus supplied can be used directly or for charging a storage battery disposed within power supply 22. Further details concerning the various alternatives usable to energize power supply 22 are not discussed herein, since they do not directly relate to the present invention.

A controller 24 in the first embodiment of fixture 20 is connected to a heat source 26 and to a separate light source 28. Preferably, light source 28 comprises a plurality of LEDs; however, it is also contemplated that other types of solid state light sources such as laser diodes, VCSELs, filament lamps, or electroluminescent devices can be used instead. Light source 28 emits the light that is employed for PDT after the photoreactive agent is infused into the abnormal tissue comprising tumor 12. Accordingly, light emitted by light source 28 has a characteristic waveband corresponding to an absorption waveband of the photoreactive agent.

In this embodiment, heat source 26 comprises either a light source or a resistance element that produces heat due to the flow of an electrical current through the device. Although a separate heat source is illustrated, light source 28 can instead be used to both provide heating of the treatment site and supply light to implement PDT. Thus, the light source can be initially energized to heat the treatment site, then de-energized until after the drug is administered, and re-energized to provide light of the required waveband to effect the PDT. However, it is preferable to use heat source 26 separate from light source 28, since more versatile control of the two sources is then possible. Unlike light source 28, heat source 26 emits energy within a waveband that is substantially different than the absorption waveband of the photoreactive agent. Instead, the waveband of energy emitted by the heat source is suitable for supplying heat to tissue at the treatment site.

Increasing the temperature of the tissue at the treatment site provides several benefits in connection with administering PDT. Specifically, the elevated temperature of the tissue caused by energy emitted from heat source 26 is believed to cause an increase in the flow of blood, both in the normal tissue surrounding tumor 12, and in the vascular system of the tumor itself. The increased flow of blood is believed to enhance the perfusion of the photoreactive agent or other drug that is injected into the abnormal tissue at the treatment site.

The preheating of the treatment site to a temperature less than 40°C for a time interval of from 20-60 minutes prior to administering PDT is optionally combined with heating of the treatment site after (or while) PDT is administered. The elevated temperature of the tissue in tumor 12 prior to administering PDT is believed to enhance the effects of PDT by increasing drug uptake into the abnormal tissue at the treatment site, substantially improving the efficacy of the therapy. Thus, more abnormal tissue is killed for a given exposure time, compared to the result that would be obtained absent preheating of the tissue at the

treatment site. It is expected that substantial further benefits can be achieved after PDT is administered, by heating the treatment site to a temperature in the range of 40°-45°C for a time interval of from 20-60 minutes. The time and temperature parameters for any hyperthermia treatment applied, before, during, and after PDT is administered will likely vary depending upon the type of abnormal tissue being treated, the power dissipated by the heat source, the type of drug being infused into the treatment site, and other variables. Thus, more specific values for these variables will depend upon empirical clinical results yet to be determined.

To avoid heating normal tissue to a level that might cause vascular damage, a temperature sensor 30 is provided in fixture 20 to monitor the temperature at the treatment site. Temperature sensor 30 produces a signal in response to the temperature of the tissue that is input to controller 24. Controller 24 in turn controls an electrical current supplied to energize heat source 26 to maintain the temperature at a set point and/or to prevent the temperature of the tissue from exceeding a predefined level at which vascular damage might be expected.

FIGURE 7 illustrates a preferred embodiment of temperature sensor 30, wherein the temperature sensor comprises a thermocouple that is disposed on the fixture. Temperature sensor 30 is coupled through leads 60 and 62 to a reference junction 64, which preferably simulates a predefined temperature, such as the ice point (0°C) of water. The voltage differential between temperature sensor 30, which is exposed to a temperature T_s , and the reference point, which is nominally at a reference temperature T_R , is indicative of the temperature sensed by temperature sensor 30. It is also contemplated that other types of temperature sensors, such as a resistance temperature device, or a thermistor could be used instead of a thermocouple junction for monitoring the temperature at the treatment site. These and other types of temperature sensors are well known to those of ordinary skill in the art.

After applying heat to the tumor for a predefined period of time, e.g., for 20-60 minutes or sufficiently long to achieve a desired temperature rise at the site, as determined by temperature sensor 30, heat source 26 is de-energized by controller 24. Either during or after heating of the abnormal tissue in tumor 12 and the surrounding tissue, the photoreactive agent is injected into tumor 12. As noted above, the increased temperature of the abnormal tissue comprising the tumor increases the perfusion of the photoreactive agent throughout the tumor. Controller 24 deactivates heat source 26 and activates light source 28 to effect

PDT in a sequence that depends upon the particular type of protocol desired. As noted above, the heat source can be selectively energized to heat the tissue at the treatment site, before, during, and/or after PDT is administered.

Following administration of PDT, heat is applied to the treatment site for an appropriate time, e.g., for 20-60 minutes, so as to elevate the temperature of the treatment site to a desired level, e.g., 40°-45°C for a desired time, e.g., 20-60 minutes. The efficacy of the PDT treatment or other drug therapy is improved because of the elevated temperature of the treatment site. It may also be desirable to apply heat to the treatment site during PDT to further improve the efficacy of the therapy.

In the preferred embodiment, PDT probe 14 is designed to be left in place within the patient's body for an extended period of time, during which PDT is conducted. However, it is also contemplated that other types of PDT probes may be used that are not designed to be implanted. Such probes will include a substantially higher intensity light source to effect PDT during a shorter period of time, e.g., while an internal treatment site is exposed during a surgical procedure, or to an external treatment site. For some types of tumors, it is possible that even a relatively low intensity light source can have the required effect upon the abnormal tissue as a result of the improvements achieved by applying heat to the treatment site. Accordingly, such a probe might effectively be used during a surgical operation, while the treatment site is exposed. In contrast, an implantable probe is designed to be left in place within a patient's body at the treatment site. The implantable probe may be placed endoscopically or while the treatment site is exposed by an incision.

Referring now to FIGURE 3, a second embodiment of a fixture 20' is shown. Fixture 20' is identical to fixture 20, except that on fixture 20', the heat source and light source are combined and comprise an array of heat emitting and PDT LEDs 32. Controller 24 is coupled to this array and determines whether the heat emitting LEDs or PDT LEDs are energized. The heat emitting LEDs preferably emit light in the infrared waveband. Again, temperature sensor 30 provides a signal indicative of the temperature at the treatment site for purposes of controlling the heat source LEDs and for preventing an excessive temperature rise at the treatment site, which might cause vascular damage to the normal tissue surrounding the tumor.

Referring to FIGURE 8, further details of PDT probe 14 are illustrated, showing an array of heat LEDs and PDT LEDs 32 enclosed in a transparent

biocompatible envelope 82. In this probe, an elongate substrate strip 70 includes two parallel conductive traces 72 and 74 formed on a surface thereof. A plurality of heat source LEDs 76 are arranged in spaced-apart array, so that the cathodes of each of the LEDs comprising the heat source are coupled electrically to conductive trace 74. Aluminum flywires 80 (or other conductors) are connected to the anode of each of the LEDs comprising the heat source and extend over to conductive traces 72, where they are electrically coupled. Similarly, PDT LEDs 78 have their cathodes electrically mounted on conductive trace 72 and an aluminum flywire 80 extends from the anode of each of the PDT LEDs to connect electrically to conductive trace 74. Depending upon the polarity of DC voltage applied across conductive traces 72 and 74 by controller 24, either the heat source LEDs or PDT LEDs will be energized. However, it will be apparent that only one of these two types of LEDs is energized at a time, based upon the polarity of the DC voltage applied to the two conductive strips. Thus, controller 24 initially energizes the heat source LEDs to heat the treatment site to the desired temperature, and then changes the polarity applied to conductive traces 72 and 74 to de-energize the heat source LEDs and energize the PDT LEDs. Those of ordinary skill in the art will appreciate that other techniques for selectively energizing the heat source and PDT LEDs can be used besides the approach used in this preferred embodiment. For example, separate pairs of conductive traces may be coupled to the heat source LEDs and to the PDT LEDs so that by selectively applying the appropriate DC voltage to the conductive traces connected to either the heat source LEDs or PDT LEDs, the controller can selectively control the types of LEDs energized at any given time. Further, if an AC voltage is applied to the probe, both sets of LEDs will be energized, one set by the positive waveform and the other set of LEDs by the negative waveform. Each set of LEDs (or each set of other types of light emitting devices) can be independently controlled to emit light of selected magnitude by independently controlling the magnitude or duration of the positive and negative waveform portions of the AC voltage applied thereto, as will be understood by those of ordinary skill in the art. Pulsed DC voltage can also be applied to independently control the intensity of each set of LEDs or other light sources as a function of the duty cycle of the respective positive and negative DC pulses.

In FIGURE 4, a fixture 34 is illustrated that differs from fixture 20 because a controller 36 is separate from fixture 34 instead of being included on it. Specifically, controller 36 is either disposed at a separate location internally

within the patient's body, or is coupled to the fixture through leads that extend externally of the patient's body. In all other respects, fixture 34 is identical to fixture 20. By moving controller 36 to a point separate from fixture 34, the size of the fixture may be reduced, since the elements comprising controller 36 need not
5 be fitted within the fixture.

A fixture 34' is shown in FIGURE 5 that is identical to fixture 20' in FIGURE 3, except that a controller 36 is not included in fixture 34' with the temperature sensor and array of heat source and PDT LEDs. The same comments regarding controller 36 apply in connection to the embodiment of FIGURE 5.

10 In FIGURE 6, details of a data transmitting section 40 of the controller that is optionally used for transmitting a temperature telemetry signal from inside the patient's body and details of an external receiving section 50 for receiving the telemetry signal are shown. When data transmitting section 40 is employed, the temperature sensor signal produced by temperature sensor 30 is input to an
15 amplifier 42, which amplifies the signal, increasing its voltage. The amplified signal from amplifier 42 is input to a radio frequency (RF) transmitter 44, where it is used to modulate an RF signal that is transmitted by an antenna coil 46. The signal transmitted by antenna coil 46 comprises the temperature telemetry data signal that is picked up by an antenna coil 52 in receiving section 50, which is
20 disposed outside the patient's body. An RF receiver 54 demodulates the signal from antenna coil 52, recovering the temperature at the treatment site. This temperature appears on a temperature display 56 so that it can be monitored by a physician or other medical personnel. As a further option, it may be desirable for the physician to be able to transmit a signal back to the controller to modify the
25 set point limit used in controlling the heat source. To enable that option, the controller must also be provided with a receiver section and must respond to an externally transmitted signal that modifies the set point limit.

In FIGURE 6A, further details of controller 24/36 are illustrated. Amplifier 42 is again used to amplify the temperature sensor signal, increasing its
30 voltage. The amplified signal from amplifier 42 and a predetermined limit set point are input to a limit comparator 58. If the temperature of the tissue at the treatment site exceeds the limit set point, limit comparator 58 de-energizes the heat source/heat source LEDs by interrupting the electrical current from the power supply to protect the normal tissue adjacent the treatment site from harm due to
35 overheating. As those of ordinary skill in the art will understand, a more sophisticated temperature control scheme (not shown) can be used in place of the

limit comparator to continuously maintain the temperature of the tissue at the treatment site at a desired set point level.

5 In addition to improving the perfusion of a photoreactive agent into the treatment site, it is also contemplated that the heat applied to a treatment site prior to initiating PDT can be used to improve the rate at which other types of drugs are perfused throughout the treatment site. Such drugs might presensitize the tumor site to enhance PDT or may improve the binding of the photoreactive agent to the abnormal tissue at the treatment site. Examples of drugs that might be used include heat sensitive liposomes and antibody conjugates.

10 Although the present invention has been described in connection with the preferred form of practicing it, those of ordinary skill in the art will understand that many modifications can be made thereto within the scope of the claims that follow. Accordingly, it is not intended that the scope of the invention in any way be limited by the above description, but instead be determined entirely by
15 reference to the claims that follow.

The invention in which an exclusive right is claimed is defined by the following:

1. A method for increasing a perfusion of a drug through tissue at a treatment site where photodynamic therapy is to be administered, comprising the steps of:

(a) positioning a fixture that emits light for use in administering the photodynamic therapy, so that the fixture is disposed adjacent to the treatment site, said fixture further including means for providing heat;

(b) energizing the means for providing heat to supply heat to the tissue at the treatment site, said heat raising the temperature of the tissue; and

(c) delivering the drug to the tissue at the treatment site, an elevated temperature of the tissue caused by the heat increasing the perfusion of the drug through the tissue at the treatment site to enhance an effect of the drug on the tissue.

2. The method of Claim 1, wherein the drug comprises a photoreactive agent, further comprising the step of supplying light from a light source on the fixture to irradiate the tissue at the treatment site after the perfusion of the photoreactive agent through the tissue has been increased by heating the tissue, said light being used to administer the photodynamic therapy.

3. The method of Claim 1, wherein the fixture includes a plurality of light sources, said means for providing heat comprising at least a portion of the light sources.

4. The method of Claim 2, wherein the fixture includes:

(a) a first light source that emits light having a first waveband that substantially overlaps a characteristic absorption waveband of the drug delivered to the tissue at the treatment site, said first light source being energized to administer the photodynamic therapy; and

(b) a second light source that emits light having a second waveband substantially different from the first waveband, said second light source comprising the means for providing heat, light emitted by the second light source thus heating the tissue, but generally not effecting the photodynamic therapy.

5. The method of Claim 2, wherein the means for providing heat comprise a light source that is also used for emitting the light employed to administer the photodynamic therapy.

6. The method of Claim 5, wherein the light source comprises an array of light emitting solid state devices.

7. The method of Claim 1, further comprising the steps of:

(a) monitoring a temperature of the tissue at the treatment site, producing a signal indicative of the temperature;

(b) controlling the means for providing heat in response to the signal indicative of the temperature of the tissue at the treatment site so that said temperature does not exceed a level that would cause vascular damage at the treatment site.

8. The method of Claim 1, wherein the treatment site is internal to a patient's body and the fixture is disposed at the internal treatment site to provide heat and administer the photodynamic therapy, said fixture comprising a probe that is adapted to be left within the patient's body for an extended period of time, while the photodynamic therapy is administered.

9. The method of Claim 1, wherein the drug is used for a medical treatment other than the photodynamic therapy.

10. The method of Claim 1, wherein the means for providing heat comprise a resistance heating element that produces heat in response to an electrical current flowing through the resistance element.

11. The method of Claim 1, wherein the treatment site is heated to an elevated temperature prior to delivering the drug to the tissue at the treatment site.

12. The method of Claim 1, wherein the drug is carried to the treatment site by a heat sensitive drug carrier that releases the drug when the treatment site is heated to an elevated temperature.

13. Apparatus for increasing a perfusion of a drug through tissue at a treatment site where photodynamic therapy is to be administered, comprising:

(a) a fixture configured to be placed at the treatment site, for administering the photodynamic therapy; and

(b) means for heating the tissue at the treatment site to increase the perfusion of the drug into the tissue, said means for heating being disposed on the fixture.

14. The apparatus of Claim 13, further comprising a light source disposed on the fixture, wherein the treatment site is disposed internally within a patient's body, and wherein the fixture comprises a probe that is adapted to be inserted internally within the patient's body at the treatment site, said light source being capable of emitting light that is directed toward the tissue at the treatment site to effect the photodynamic therapy.

15. The apparatus of Claim 14, wherein said drug comprises a photoreactive agent having a characteristic light absorption waveband, and wherein the light source comprises a plurality of light emitting devices mounted to the fixture, at least a portion of said light emitting devices producing light having a waveband corresponding to the characteristic absorption waveband of the photoreactive agent.

16. The apparatus of Claim 15, wherein the means for heating the tissue comprise a plurality of light emitting devices that are mounted to the fixture and produce light having a waveband substantially different than the characteristic absorption waveband of the photoreactive agent.

17. The apparatus of Claim 16, wherein the means for heating and the light source are each selectively separately controlled.

18. The apparatus of Claim 13, wherein the means for heating comprise a plurality of light emitting devices arranged in a spaced-apart array.

19. The apparatus of Claim 13, further comprising a temperature sensor disposed on the fixture, said temperature sensor producing a signal indicative of a temperature of the tissue at the treatment site.

20. The apparatus of Claim 19, further comprising means for controlling the means for heating in response to the signal indicative of the temperature, so that the temperature of the tissue does not exceed a level that causes vascular damage.

21. The apparatus of Claim 20, wherein the means for controlling are disposed internally within a patient's body.

22. The apparatus of Claim 20, wherein the means for controlling are disposed externally of a patient's body.

23. The apparatus of Claim 20, further comprising a transmitter coupled to the fixture to receive the signal produced by the temperature sensor for transmission as a wireless telemetry signal from inside the patient's body.

24. The apparatus of Claim 23, further comprising a receiver disposed outside the patient's body, said receiver receiving the wireless telemetry signal, and displaying the temperature of the tissue.

25. The apparatus of Claim 20, wherein the means for controlling are coupled to the temperature sensor via a lead that extends from the fixture and is disposed inside the patient's body.

26. A method for increasing an efficacy of a photodynamic therapy, comprising the steps of:

(a) applying a photoreactive agent to a treatment site, said photoreactive agent have a characteristic absorption waveband;

(b) directing light toward the treatment site from a fixture used to administer the photodynamic therapy, said light having a waveband substantially corresponding to the characteristic absorption waveband of the photoreactive agent; and

(c) heating the treatment site after the photodynamic therapy has been administered using a heat source that is also disposed on said fixture, thereby raising the temperature of the treatment site to increase the efficacy of the photodynamic therapy.

27. The method of Claim 26, wherein the heat source is also used to produce the light directed toward the treatment site.

28. The method of Claim 26, wherein the heat source comprises a source of light that is not used for administering the photodynamic therapy.

29. The method of Claim 26, wherein the heat source comprises a resistive heating device.

30. The method of Claim 26, further comprising the steps of:

- (a) monitoring a temperature of the treatment site, producing a signal indicative of the temperature;
- (b) controlling heat source in response to the signal indicative of the temperature of the treatment site so that said temperature does not exceed a level that would cause vascular damage.

AMENDED CLAIMS

[received by the International Bureau on 13 November 1997 (13.11.97);
original claims 4,14,15,19,21,22 and 24 amended;
remaining claims unchanged (3 pages)]

1. A method for increasing a perfusion of a drug through tissue at a treatment site where photodynamic therapy is to be administered, comprising the steps of:

(a) positioning a fixture that emits light for use in administering the photodynamic therapy, so that the fixture is disposed adjacent to the treatment site, said fixture further including means for providing heat;

(b) energizing the means for providing heat to supply heat to the tissue at the treatment site, said heat raising the temperature of the tissue; and

(c) delivering the drug to the tissue at the treatment site, an elevated temperature of the tissue caused by the heat increasing the perfusion of the drug through the tissue at the treatment site to enhance an effect of the drug on the tissue.

2. The method of Claim 1, wherein the drug comprises a photoreactive agent, further comprising the step of supplying light from a light source on the fixture to irradiate the tissue at the treatment site after the perfusion of the photoreactive agent through the tissue has been increased by heating the tissue, said light being used to administer the photodynamic therapy.

3. The method of Claim 1, wherein the fixture includes a plurality of light sources, said means for providing heat comprising at least a portion of the light sources.

4. The method of Claim 2, wherein the fixture includes:

(a) a first light source that is adapted to emit a light having a first waveband that substantially overlaps a characteristic absorption waveband of the drug delivered to the tissue at the treatment site, said first light source being energized to administer the photodynamic therapy; and

(b) a second light source that is adapted to emit a light having a second waveband substantially different from the first waveband, said second light source comprising the means for providing heat, the light emitted by the second light source thus heating the tissue, but generally not effecting the photodynamic therapy.

13. Apparatus for increasing a perfusion of a drug through tissue at a treatment site where photodynamic therapy is to be administered, comprising:

(a) a fixture configured to be placed at the treatment site, for administering the photodynamic therapy; and

(b) means for heating the tissue at the treatment site to increase the perfusion of the drug into the tissue, said means for heating being disposed on the fixture.

14. The apparatus of Claim 13, further comprising a light source disposed on the fixture, wherein the treatment site is disposed internally of a patient's body, and wherein the fixture comprises a probe that is adapted to be inserted internally of the patient's body at the treatment site, said light source being capable of emitting a light that is directed toward the tissue at the treatment site to effect the photodynamic therapy.

15. The apparatus of Claim 14, wherein the light source comprises a plurality of light emitting devices mounted to the fixture, at least a portion of said light emitting devices being adapted to produce a light having a waveband corresponding to a characteristic absorption waveband of a photoreactive agent comprising the drug.

16. The apparatus of Claim 15, wherein the means for heating the tissue comprise a plurality of light emitting devices that are mounted to the fixture and produce light having a waveband substantially different than the characteristic absorption waveband of the photoreactive agent.

17. The apparatus of Claim 16, wherein the means for heating and the light source are each selectively separately controlled.

18. The apparatus of Claim 13, wherein the means for heating comprise a plurality of light emitting devices arranged in a spaced-apart array.

19. The apparatus of Claim 13, further comprising a temperature sensor disposed on the fixture, said temperature sensor being adapted to produce a signal indicative of a temperature of the tissue at the treatment site.

20. The apparatus of Claim 19, further comprising means for controlling the means for heating in response to the signal indicative of the temperature, so that the temperature of the tissue does not exceed a level that causes vascular damage.

21. The apparatus of Claim 20, wherein the means for controlling are adapted to be disposed internally of a patient's body.

22. The apparatus of Claim 20, wherein the means for controlling are adapted to be disposed externally of a patient's body.

23. The apparatus of Claim 20, further comprising a transmitter coupled to the fixture to receive the signal produced by the temperature sensor for transmission as a wireless telemetry signal from inside the patient's body.

24. The apparatus of Claim 23, further comprising a receiver disposed outside the patient's body, said receiver being adapted to receive the wireless telemetry signal and display the temperature of the tissue.

25. The apparatus of Claim 20, wherein the means for controlling are coupled to the temperature sensor via a lead that extends from the fixture and is disposed inside the patient's body.

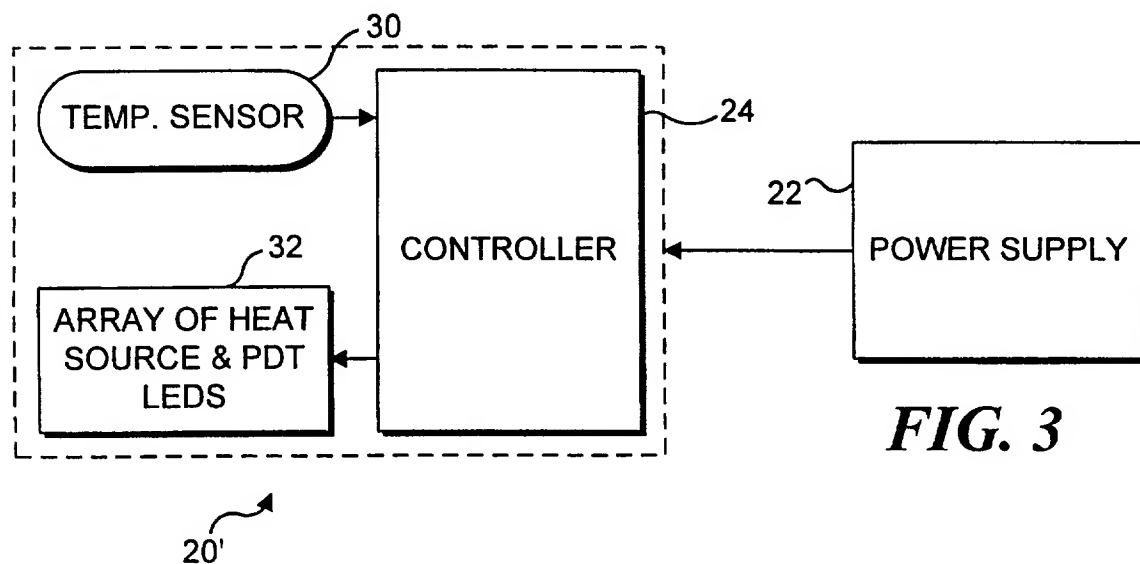
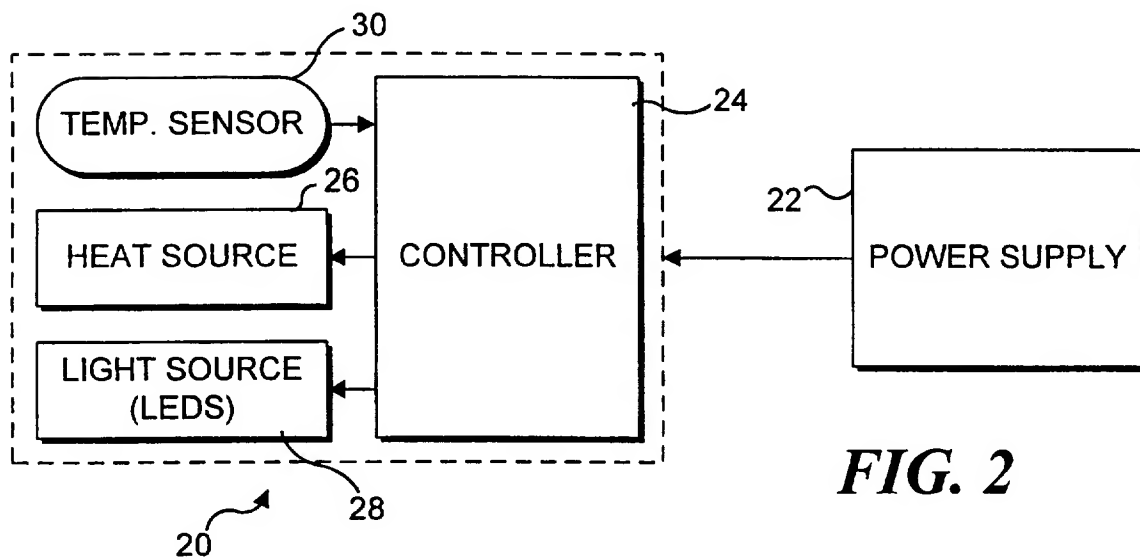
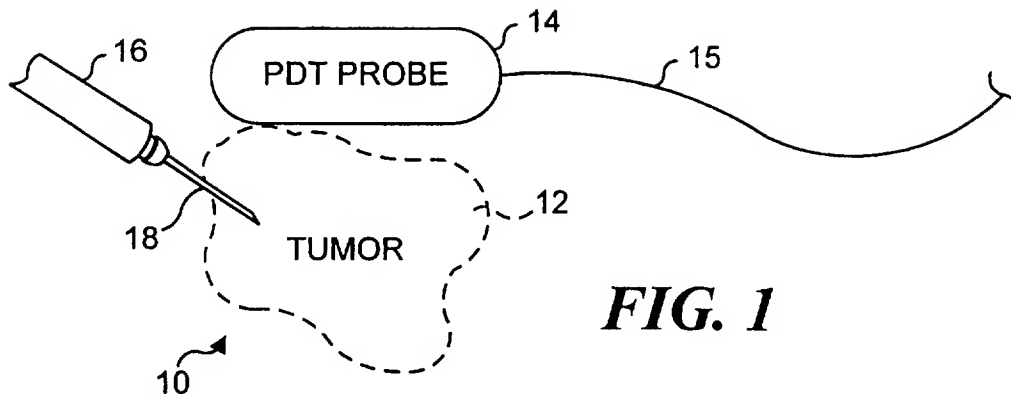
26. A method for increasing an efficacy of a photodynamic therapy, comprising the steps of:

(a) applying a photoreactive agent to a treatment site, said photoreactive agent have a characteristic absorption waveband;

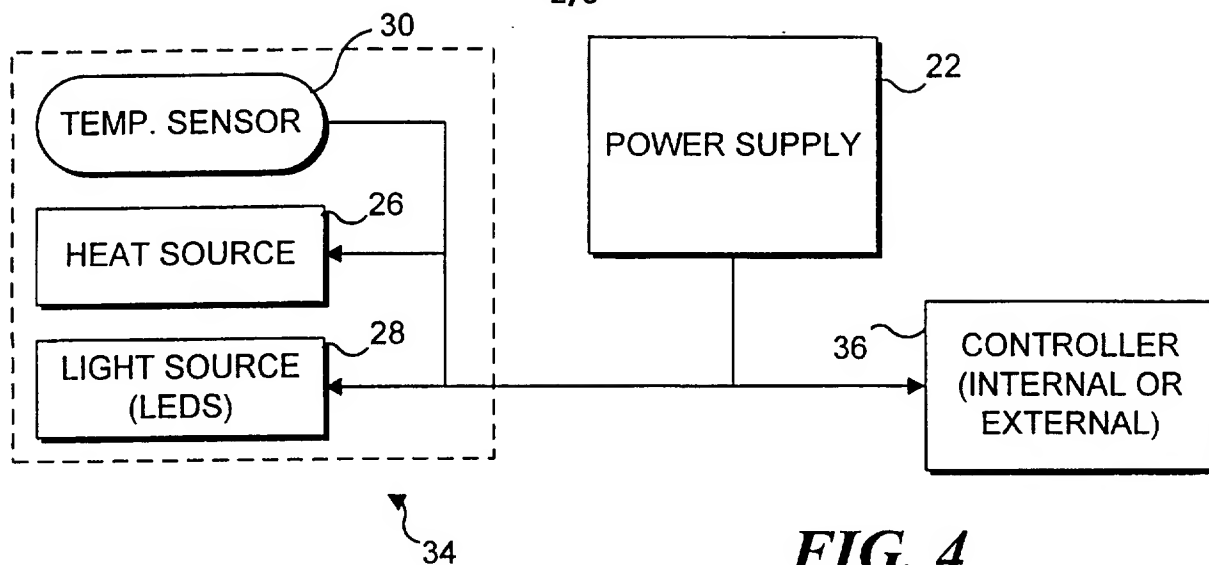
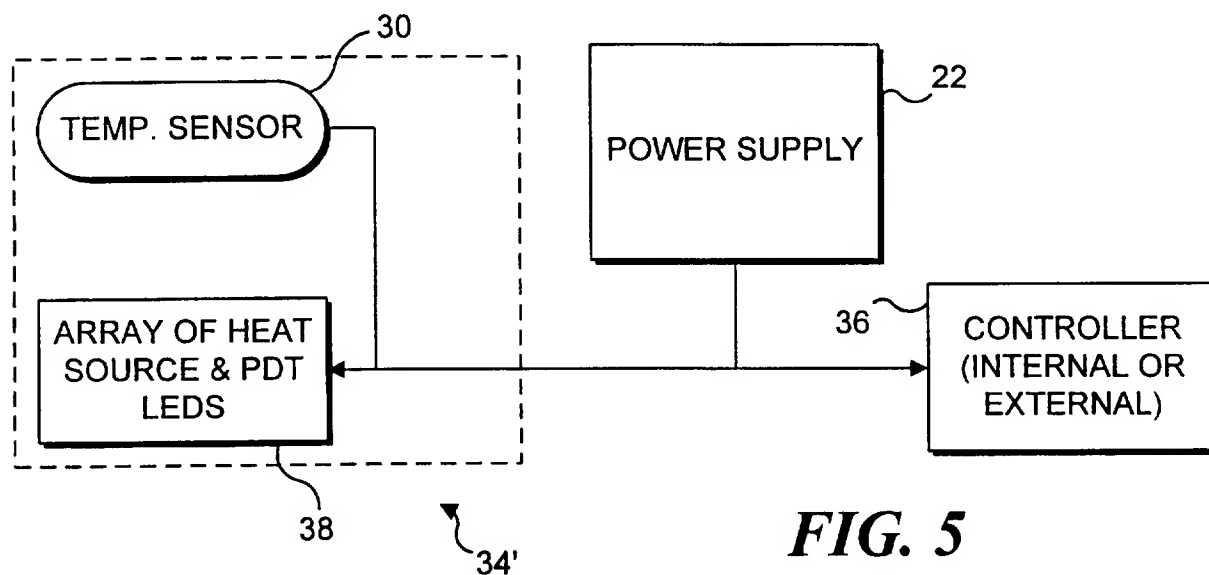
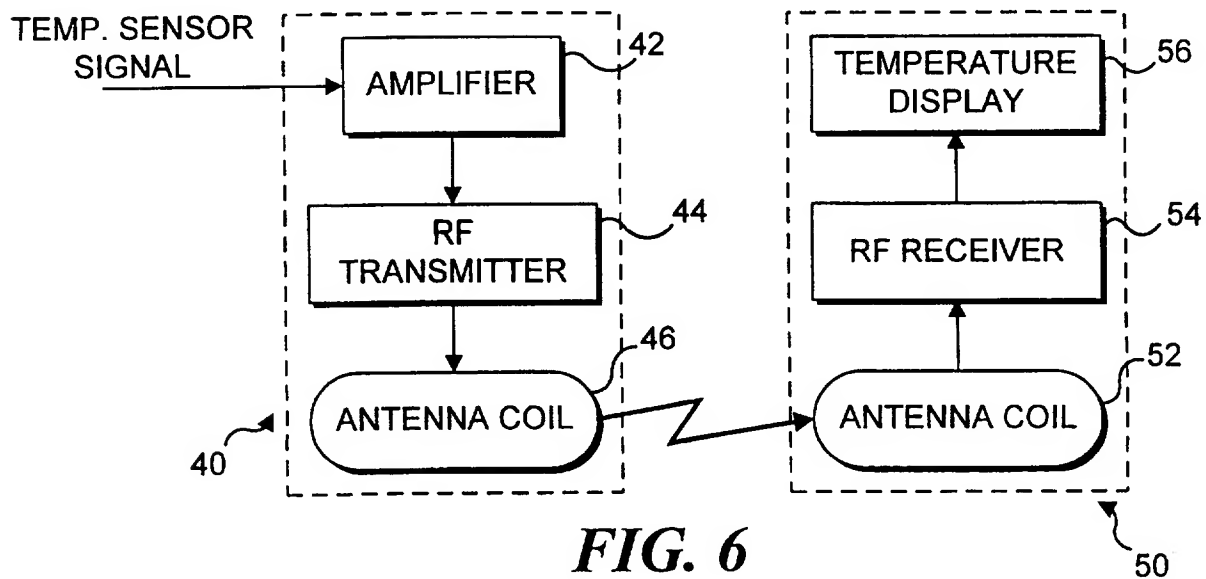
(b) directing light toward the treatment site from a fixture used to administer the photodynamic therapy, said light having a waveband substantially corresponding to the characteristic absorption waveband of the photoreactive agent; and

(c) heating the treatment site after the photodynamic therapy has been administered using a heat source that is also disposed on said fixture, thereby raising the temperature of the treatment site to increase the efficacy of the photodynamic therapy.

27. The method of Claim 26, wherein the heat source is also used to produce the light directed toward the treatment site.



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**FIG. 4****FIG. 5****FIG. 6**

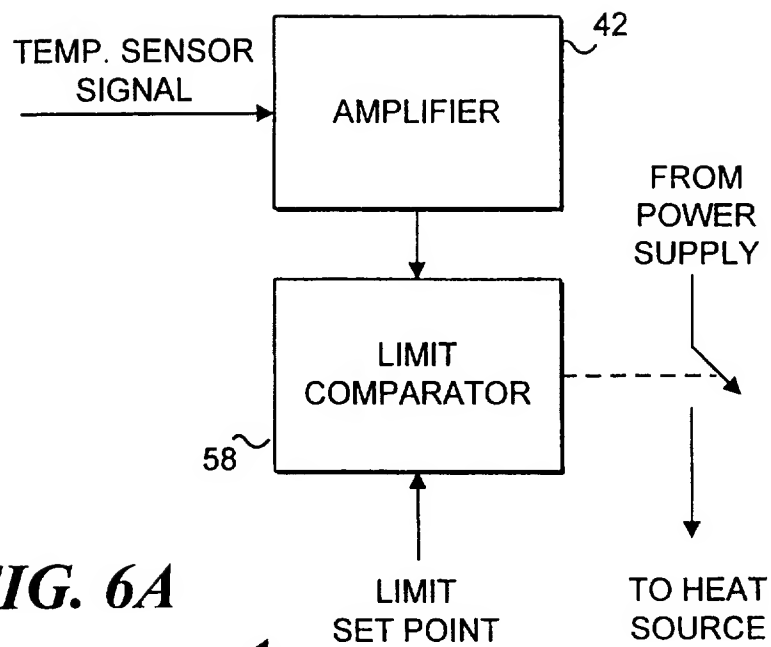


FIG. 6A

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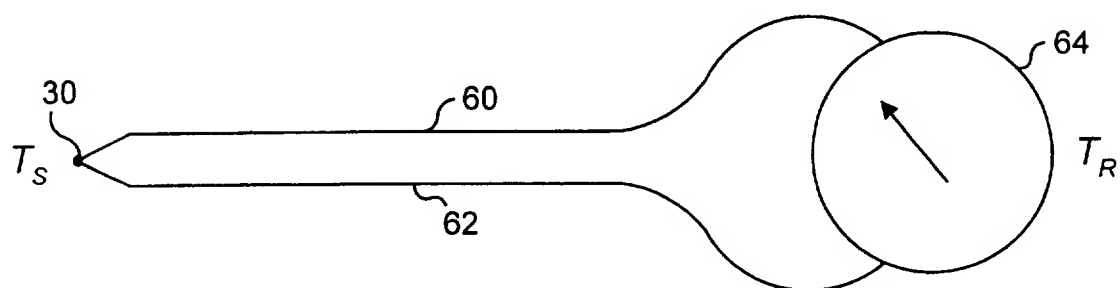


FIG. 7

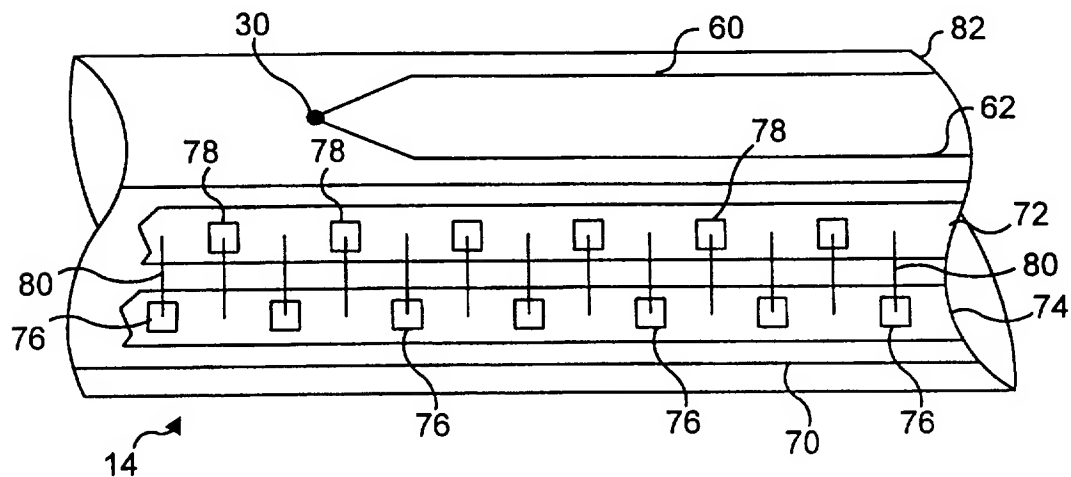


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/11050

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 1/30

US CL :604/20, 49

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/19-22, 49

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

Search Terms: photoactive, PDT, photodynamic therapy, LED, light emitter, waveband, wavelength

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,445,608 A (CHEN et al.) 29 August 1995, entire reference.	1-10, 13-27, 29, 30 ----- 9-12, 28, 29
X --- Y	US 4,822,335 A (KAWAI et al.) 18 April 1989, entire reference.	1-6, 9, 10, 13, 18, 26, 27, 29 ----- 7, 8, 11, 12, 14-17, 19-22, 28, 30



Further documents are listed in the continuation of Box C.



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24 JULY 1997

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ELLEN TAO

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

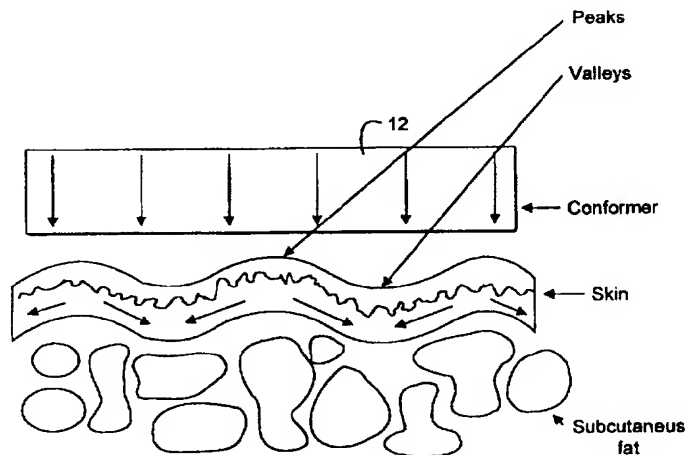
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,556,057 A (HIRUMA et al.) 03 Dec ember 1985, entire reference.	1-4, 8-10, 13-17, 26-29 ----- 7, 11, 12, 19-22, 28, 30
X --- Y	US 4,957,481 A (GATENBY) 18 September 1990, col. 2, line 68.	1-3, 5, 8-10, 13- 15, 26, 27, 29 ----- 7, 11, 12, 19-22, 28, 30
Y	US 5,257,970 A (DOUGHERTY) 02 November 1993, col. 1, lines 55-58; and claims 3 and 5.	11-12, 28
Y	US 5,405,369 A (SELMAN et al.) 11 April 1995, col. 8, lines 4-6; and col. 9, lines 42-44.	7, 19-22, 28, 30



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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			(43) International Publication Date: 12 February 1998 (12.02.98)
(21) International Application Number: PCT/US97/13607 (22) International Filing Date: 4 August 1997 (04.08.97) (30) Priority Data: 60/023,377 5 August 1996 (05.08.96) US 08/827,237 28 March 1997 (28.03.97) US (60) Parent Application or Grant (63) Related by Continuation US 08/827,237 (CIP) Filed on 28 March 1997 (28.03.97) (71)(72) Applicant and Inventor: KNOWLTON, Edward, W. [US/US]; 5478 Blackhawk Drive, Danville, CA 94506 (US). (74) Agent: DAVIS, Paul; Wilson, Sonsini, Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>	

(54) Title: APPARATUS FOR TISSUE REMODELING



(57) Abstract

An apparatus to modify a skin surface or a soft tissue structure underlying the skin surface includes a template with a mechanical force application surface and a receiving opening to receive a body structure. The mechanical force application surface is configured to receive the body structure and apply pressure to the soft tissue structure. An energy delivery device is coupled to the template. The energy delivery device is configured to deliver sufficient energy to the template to form a template energy delivery surface.

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APPARATUS FOR TISSUE REMODELING

BACKGROUND OF THE INVENTION

10 Field of the Invention

This invention relates to a method and apparatus for modifying a soft tissue structure underlying a skin surface, and more particularly to a method and apparatus which applies a mechanical force and electromagnetic energy to the soft tissue structure.

15 Description of Related Art

The correction of a deformity or the esthetic enhancement of a soft tissue structure is determined by the balance of the skin envelope as the container and soft tissue volume as the contents of the container. An appropriate balance between these two components is essential in achieving a successful outcome.

20 Most plastic surgery procedures are based upon the resection or addition of a soft tissue filler with a concomitant modification of the skin envelope. For example, a breast that has three dimensional symmetry with the opposite breast must take into account both the volume of the soft tissue and the surface area of the breast envelope that is required as a container of the tissue. Breast reconstruction after
25 mastectomy typically involves the insertion of a soft tissue replacement for the

removed breast tissue. Either an implant or a tissue flap from the patient is used as a soft tissue replacement. Expansion of the breast skin envelope is also required and is achieved with a medical device called a breast expander. While most reconstructive procedures usually involve the addition of a soft tissue filler with the expansion of the skin envelope, many esthetic procedures involve the reduction of the soft tissue contents with or without a reduction in the skin envelope.

Reduction in the volume of the soft tissue contents without a concomitant reduction in the skin envelope may lead to a relative excess of the skin envelope. The relative excess will be visualized as loose skin or elastosis. An example of esthetic enhancement is a procedure called breast reduction. This is performed in women who require reduction in the size of their breasts to alleviate shoulder, neck and back symptoms. Breast tissue is resected to reduce volume but also requires a reduction in the breast skin envelope with extensive surgical incisions. Without reduction of the skin envelope of the breast, severe ptosis (droopiness) of the breast will occur.

Another example is liposuction which may aggravate elastosis because the soft tissue content is reduced without reduction in the surface area of the skin envelope. The degree of esthetic contour reduction is limited by the preexisting looseness of the skin envelope. Typically, liposuction involves the removal of subcutaneous fat through a suction cannula inserted through the skin surface. Excess suctioning of fat will aggravate any preexisting elastosis. Any other modality that reduces subcutaneous fat through dieting or ablation of fat cells is likely to aggravate a preexisting elastosis if a concomitant reduction of the skin envelope does not occur. This is especially true in the hip and thigh area where a condition called "cellulite" is due to a preexisting looseness of skin. Many patients have a more severe looseness of skin in the hip and thigh area that would be aggravated by any fat removal. Skin tightening procedures that involve large

surgical incisions result in severe scarring to the thigh and hip area that are a poor tradeoff to any esthetic contour reduction.

There is a need for a method and apparatus to achieve skin tightening without major surgical intervention. There is a further need for a method and apparatus to achieve skin tightening by the controlled remodeling of collagen in the skin and underlying fibrous partitions of the subcutaneous fat. Still a further need exists to tighten a skin envelop with minimal skin or underlying subcutaneous tissue cell necrosis. Yet another need exists to provide a method and apparatus for the controlled remodeling of collagen in tandem with subcutaneous fat ablation in which a net tightening of the skin envelope occurs with an esthetic contour reduction.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide a method and apparatus to tighten skin.

Another object of the invention is to provide a method and apparatus to tighten skin without major surgical intervention.

Yet another object of the invention is to provide a method and apparatus to tighten skin with controlled remodeling of collagen.

A further object of the invention is to provide a method and apparatus that delivers a mechanical force and electromagnetic energy to a tissue site to change a skin surface.

A further object of the invention is to provide a method and apparatus that delivers a mechanical force and electromagnetic energy to a tissue site to change the contour of a soft tissue structure.

These and other objects of the invention are achieved in an apparatus to modify a skin surface or a soft tissue structure underlying the skin surface. A template has a soft tissue mechanical force application surface. The mechanical

force application surface is configured to apply pressure to the soft tissue structure. An energy delivery device is coupled to the template. The energy delivery device is configured to deliver sufficient energy to the template to form a template energy delivery surface.

5 In one embodiment, a template means is configured to apply the mechanical force to the soft tissue structure at the mechanical force application surface. An energy delivery means is coupled to the template means and provides a controlled delivery of electromagnetic energy to the skin surface that does not exceed 1,000 joules/cm² during a single treatment session. A combination of the mechanical
10 force and the controlled delivery of electromagnetic energy changes a contour of the soft tissue structure.

 In another embodiment, a method of operating an apparatus for modifying a structure provides an apparatus that includes a template means configured to receive a structure and apply a mechanical force. The apparatus also includes an
15 energy delivery means coupled to the template means to provide a controlled delivery of electromagnetic energy to the structure not exceeding a dose rate of 10 joules/sec/cm². Sufficient mechanical force and electromagnetic energy is delivered to the structure to remodel at least a portion of the structure.

 The mechanical force application surface can be a positive pressure
20 application surface that applies compression to the soft tissue structure or a negative pressure application surface that creates an extension of the soft tissue structure. Application of the mechanical force and delivery of the energy has a variety of different effects including but not limited to, (i) tightening the skin surface, (ii) smoothing the skin surface, (iii) improving a compliance of the skin surface, (iv) improving a flexibility of the skin surface, (v) remodeling of collagen
25 in the soft tissue structure, (vi) cleaving collagen cross-links to remodel collagen, (vii) remodeling of collagen in the soft tissue structure with reduced cell necrosis, (viii) cleaving collagen cross-links and contracting a longitudinal axis of a collagen

fibril, (ix) cleave collagen cross-links and extend a longitudinal axis of a collagen fibril, (x) cleaving collagen cross-links and shearing of a collagen fibril matrix, (xi) directing converging and diverging mechanical forces to the skin surface to smooth the skin surface and tighten the skin surface, (xii) directing converging and diverging mechanical forces to the soft tissue structure to create a three-dimensional contouring of the soft tissue structure, (xiii) creating a compressive force to collagen in the underlying soft tissue structure and (ix) delivering sufficient pressure and creating an extension force to collagen in the underlying soft tissue structure.

The mechanical force can, (i) create a compressive force to collagen in the underlying soft tissue structure, (ii) create an extension force to collagen in the underlying soft tissue structure and (iii) create a shearing force in the underlying soft tissue structure.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a cross-sectional view of a template of the present invention.

Figure 2 is a lateral section view of the template illustrated in Figure 1.

Figure 3 illustrates intramolecular cross-linking of collagen.

Figure 4 illustrates intermolecular cross-linking of collagen.

Figures 5 and 6 are two graphs illustrating a probability of collagen cleavage with changing bond strength at 37 degrees C.

Figure 7 is a top down view of a skin surface, illustrating the peaks and valleys of the surface and the vectors applied to the surface by the application of a mechanical force.

Figure 8 is a cross-sectional view of the skin surface illustrated in Figure 7.

Figure 9 is a cut-away view of the skin surface, with troughs and ridges, and underlying subcutaneous soft tissue.

Figure 10(a) is a lateral perspective view of a telescoping segment of a breast expander useful with the apparatus of Figure 1.

Figure 10(b) is a front perspective view of the breast expander of Figure 10(a).

5 Figure 10(c) illustrates a bra which functions as the template of Figure 1.

Figure 10(d) is a lateral cross-sectional perspective view of a partially expanded breast expander within a breast.

Figure 10(e) is a lateral cross-sectional perspective view of a fully expanded breast expander within a breast.

10 Figure 11 illustrates a template in the form of a garment.

Figure 12(a) illustrates a template that is positioned over a nose.

Figure 12(b) illustrates a template that is positioned over an ear.

Figure 13 is a perspective view of a template that is useful in the cervix.

Figure 14 is a cross-sectional view of the template of Figure 13.

15 Figure 15 (a) is a lateral perspective view of a template positioned over a nose.

Figure 15(b) is a perspective view of the template of Figure of 15(a)

Figure 15(a) is a front view of an orthodontic appliance that includes RF electrodes.

20 Figure 15(b) is perspective view of an orthodontic appliance template of the device of Figure 1.

Figure 15(c) is cross-sectional view of the template of Figure 15(b)

25 Figure 16 illustrates a template made of a semisolid material that becomes more conforming to underlying soft tissue upon the application of a mechanical force.

Figure 17 illustrates a template with an adherent or suction mechanical force delivery surface that permits manual manipulation of skin and soft tissue structures.

Figure 18 is a schematic diagram of an analog embodiment of the controller for use in the apparatus of Figure 1.

Figures 19 through 22 represent a schematic block diagram of a microprocessor controlled impedance monitoring apparatus for controlling RF energy delivered by the apparatus of Figure 1.

DETAILED DESCRIPTION

Referring now to Figures 1 and 2, an apparatus 10 to modify a skin surface or a soft tissue structure underlying the skin surface. A template 12 includes a soft tissue mechanical force application surface 14 and a receiving opening 16 to receive a body structure. Mechanical force application surface 14 is configured to receive the body structure and apply pressure to soft tissue in the body structure. An energy delivery device 18 is coupled to template 12. Energy delivery device 18 is configured to deliver sufficient energy to template 12 to form a template energy delivery surface 20 at an interior of template 12.

Mechanical force application surface 14 can apply pressure, suction, adhesion and the like in order to create an extension or compression of the soft tissue collagen containing structure and/or the skin surface.

Energy delivery device 18 and an energy source may be a single unit or each can be separate. Suitable energy sources 22 include but not limited to, resistive heating, RF, coherent and incoherent light, microwave, electrical, thermal, magnetic, frictional heating, ultrasound, liquid thermal jet and cryogenic fluids. Energy delivery device 18 can form an energy delivery surface 20 in template 12 which can be the same size as mechanical force application surface 14.

Template 12 applies both a mechanical force and delivers energy to, (i) tighten the skin, (ii) smooth the surface of the skin, (iii) improve a compliance of the skin surface, (iv) improve a flexibility of the skin surface and (v) provides cellular remodeling of collagen in soft tissue anatomical structures. Mechanical

force application surface 14, (i) is at least partially conforming to the skin surface, (ii) may apply a substantially even pressure to the soft tissue anatomical structures and (iii) can apply a variable pressure to the skin surface and underlying soft tissue structures. The combined delivery of electromagnetic energy and a mechanical
5 force is used to create a three-dimensional contouring of the soft tissue structure. The amount of mechanical force applied by mechanical force application surface 14, (i) is sufficient to achieve a smoothing effect of the skin surface, (ii) can be less than the tensile strength of collagen in tissue and (iii) is sufficient to create vectors that cleave collagen cross-links to remodel collagen containing structures.

10 Template 12 can include a reverse thermal gradient device 23 which may be a closed loop cooling channel positioned in the interior of template 12. Reverse thermal gradient device can be positioned at mechanical force application surface 14.

 A sensor 21 is positioned at template energy delivery surface to monitor
15 temperature, impedance and the like. Suitable sensors 21 include impedance and thermal devices. Sensor 21 is used to control the delivery of energy and reduce the chance of cell necrosis at the surface of the skin as well as damage to underlying soft tissue structures. Sensor 21 is of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. A suitable
20 thermal sensor 21 includes a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like.

 Apparatus 10 is designed for the specific energy requirements of each type of bond within the collagen matrix. Collagen crosslinks may be either
25 intramolecular (hydrogen bond) or intermolecular (covalent and ionic bonds). Hydrogen bonds are disrupted by heat. Covalent bonds may be cleaved with the stress created from the hydrogen bond disruption and the application of an external mechanical force. Cleavage of ionic bonds may be achieved with an alternating

electrical moment in addition to the application of an external mechanical force that is applied by template 12. The strength of a hydrogen bond is relatively weak and can be thermally disrupted without ablation of tissue. The in vitro thermal cleavage of the hydrogen bond crosslinks of tropocollagen can result in the molecular contraction of the triple helix up to one third of its original length. However, in vivo collagen exists in fibrils that have extensive intermolecular crosslinks that are covalent or ionic. These covalent and ionic crosslinks are stronger and cannot be easily disrupted with heat. These intermolecular bonds are the main structural determinants of matrix strength and morphology. In vivo thermal disruption of intramolecular hydrogen bonds will not by itself result in a significant change in matrix morphology. As the intermolecular crosslinks are heat stable, cleavage may occur by a secondary process which can be the result of thermal disruption of intramolecular hydrogen bonds. In the non-polar region of the collagen fibril, intermolecular covalent bonds predominate (intramolecular covalent bonds are also present but are fewer in number).

These intermolecular covalent crosslinks increase with age, see Figures 3 and 4. As a result, the solubility of the collagen matrix in a soft tissue structure is reduced with this maturation process. Although tensile strength is increased, the collagen containing tissue becomes less compliant. Cleavage of an intermolecular bond requires approximately 1 ev of energy and can not be accomplished by heat without thermal ablation of tissue. In addition, covalent bonds are not strongly polar and will not be significantly affected by an RF current at this reduced power level. Cleavage of intermolecular covalent bonds that result in matrix remodeling without ablation is achieved by the stress created from the thermal disruption of intramolecular hydrogen bonds. Additional remodeling stress can be provided with the application of an external force that has the appropriate orientation to the fibrils of the matrix. Ionic bonds are essentially intermolecular and are present in the polar regions of the fibril. Although slightly weaker than covalent bonds, thermal

disruption cannot occur without ablation of tissue. An RF field is an effective means to cleave these bonds and is created by the an in phase alternating ionic motion of the extracellular fluid. Frequency modulation of the RF current may allow coupling to the ionic bonds in the polar regions of the fibril. Remodeling of a target site may be optimized by the selection of a band of the spectrum that is target site specific in order to reduce collateral damage. If an optimized intrinsic absorption is insufficient then a selective medium may be provided to alter the absorption in order to discriminate various soft tissue structures. This may be achieved by altering the absorption. By altering the extra-cellular fluid content of a soft tissue in specific ways, the delivery of energy to a target tissue site is achieved with minimal damage to collateral structures such as skin and adjacent soft tissue structures.

The reforming of bonds at the same bond sites will diminish the remodeling process. Relaxation phenomena may inhibited with the application of an external mechanical force that separates bond sites but allows the reforming of these covalent and ionic bonds in a lengthened or contracted morphology. This can be the underlying biophysical process that occurs with the controlled remodeling of the collagen matrix. Ground substance may also function to diminish relaxation of crosslinks through competitive inhibition. Chondroitin sulfate is a highly charged molecule that is attached to a protein in a "bottle brush" configuration. This configuration promotes attachment at polar regions of the fibril and reduces the relaxation of ionic bonds in this region. As a consequence, immature soluble collagen, which has fewer intermolecular crosslinks and contains a higher concentration of ground substance, may be more easily remodeled. The induction of scar collagen through the wound healing sequence may also facilitate the remodeling process within a treatment area.

The cleavage of a collagen crosslink requires has an energy threshold. Collagen cleavage in tissue is a probability event. There is a greater probability

that a collagen bond will be cleaved with higher temperatures. Cleavage of collagen bonds will occur at lower temperatures but at a lower frequency. Low level thermal cleavage is frequently associated with relaxation phenomena in which there is not a net change in molecular length. An external force that mechanically
5 cleaves the fibril may reduce the probability of relaxation phenomena. The application of an external force will also provide a means to lengthen or contract the collagen matrix at lower temperatures while reducing the potential of surface ablation. The cleavage of crosslinks with collagen remodeling may be occurring at a basal metabolic temperature that is expressed morphologically as the process of
10 aging. Although the probability for significant cleavage in a short period of time is small, aging may be expressed as a low level steady state of collagen remodeling with the external force of gravity that becomes very significant over a period of decades. Hydrogen bonds which are relatively weak (.2 ev to .4 ev) are formed within the tertiary structure of the tropocollagen molecule.

15 Thermal disruption of these bonds can be achieved without ablation of tissue, i.e., cell necrosis. The probability of hydrogen bond disruption at a certain temperature can be predicted by statistical thermodynamics. If a Boltzmann distribution is used to calculate the probability of bond disruption then a graph illustrating the relationship between bond strength and the probability of bond
20 disruption at a certain temperature can be produced. Graphs of the probability of cleavage at 37 degrees centigrade with various bond strengths are shown in Figures 5 and 6.

Different morphological expressions of aging may be due to the effect of gravity upon the matrix of a particular area. In areas of the skin envelope in which
25 gravity lengthens the matrix, elastosis of skin will occur. In contrast to skin aging certain anatomical structures, such as joint ligaments, will appear to tighten with the aging process. The reduced range of motion may be due in part to the vertical vector of gravity contracting the matrix of a vertically aligned ligament. However,

most of the "tightening" or reduced range of motion of joints may not be secondary to a contracted matrix but is due to reduced flexibility of the matrix caused by increased intramolecular cross-linking that occurs with aging. Essentially, the controlled remodeling of collagen is the reversal of the aging process and involves the reduction in the number of intermolecular crosslinks. As a result the remodeled matrix becomes less brittle. Greater flexibility of the soft tissue has several functional advantages including an increased range of motion of component joints.

When the rate of thermal cleavage of intramolecular crosslinks exceeds the rate of relaxation (reforming of hydrogen bonds) then the contraction of the tertiary structure of the molecule can be achieved. No external force is required for this process to occur. Essentially, the contraction of the tertiary structure of the molecule creates the initial intermolecular vector of contraction. The application of an external mechanical force during thermal cleavage will also affect the length of the collagen fibril and is determined by the overall sum of intrinsic and extrinsic vectors that is applied during a cleavage event. Collagen fibrils in a matrix exhibit a variety of spatial orientations. The matrix is lengthened if the sum of all vectors act to distract the fibril. Contraction of the matrix is facilitated if the sum of all extrinsic vectors acts to shorten the fibril. Thermal disruption of intramolecular bonds and mechanical cleavage of intermolecular crosslinks is also affected by relaxation events that restore preexisting configurations. However, a permanent change of molecular length will occur if crosslinks are reformed after lengthening or contraction of the collagen fibril. The continuous application of an external mechanical force will increase the probability of crosslinks forming alter lengthening or contraction of the fibril.

The amount of (intramolecular) hydrogen bond cleavage required will be determined by the combined ionic and covalent intermolecular bond strengths within the collagen fibril. Until this threshold is reached little or no change in the quaternary structure of the collagen fibril will occur. When the intermolecular

stress is adequate, cleavage of the ionic and covalent bonds will occur. Typically, the intermolecular cleavage of ionic and covalent bonds will occur with a ratcheting effect from the realignment of polar and non-polar regions in the lengthened or contracted fibril. The birefringence (as seen with the electron
5 microscope) of the collagen fibril may be altered but not lost with this remodeling process. The quarter staggered configuration of the tropocollagen molecules in the native fiber exhibits a 680 Å banding which either lengthens or contracts depending on the clinical application. The application of the mechanical force with template
12 during the remodeling process determines if a lengthen or contracted
10 morphology of the collagen fibril is created. An external force of contraction will result in the contraction of the tertiary and quaternary structure of the matrix. With the application of an external distraction force, intramolecular contraction may still occur from the intrinsic vector that is inherent within its tertiary structure. However, overall lengthening of the quaternary structure of the fibril
15 will occur due to the mechanical cleavage of the intermolecular bonds. Contraction of the tertiary structure with overall lengthening of the collagen fibril can alter the birefringence of the matrix. The altered periodicity will be exhibited in the remodeled matrix that will correlate to the amount of lengthening achieved.

Delivery of both electromagnetic energy and mechanical energy to the
20 selected body structure involves both molecular and cellular remodeling of collagen containing tissues. The use of low level thermal treatments over several days provides an additional way to contract skin with minimal blistering and cell necrosis. Cellular contraction involves the initiation of an inflammatory/wound healing sequence that is perpetuated over several weeks with sequential and
25 lengthy low level thermal treatments. Contraction of skin is achieved through fibroblastic multiplication and contraction with the deposition of a static supporting matrix of nascent scar collagen. This cellular contraction process is a biological threshold event initiated by the degranulation of the mast cell that releases

histamine. This histamine release initiates the inflammatory wound healing sequence.

5 Molecular contraction of collagen is a more immediate biophysical process that occurs most efficiently with electromagnetic energy delivery devices, including but not limited to RF electrodes. The clinical setting is physician controlled and requires more precise temperature, impedance, and energy delivery monitoring to avoid blistering of the skin. Measured impedance will vary with the frequency of the electromagnetic energy applied to the skin surface and/or underlying soft tissue structure.

10 Patients may be treated with one or both modalities to achieve the optimal esthetic result. Refinements to the treatment area may be required using apparatus 10 in the physician's office.

15 However, tightening of a skin surface may accentuate any preexisting contour irregularities. For this reason, conforming esthetic template 12 is used to smooth surface contour irregularities. Essentially, the application of a mechanical force upon the collagen matrix involves both contraction or distraction of the selected soft tissue structure to achieve a smoother contour. Thermal (or em) cleavage of collagen crosslinks when combined with a mechanical force creates vectors that contract, distract or shear the longitudinal axis of the fibril. A vector space is created with the combination of a scalar component (heat) and a vector (an externally applied mechanical force). The vectors within this vector space vary depending upon the specific morphology. For example, the peaks and valleys of cellulite will have different vectors when uniform external compression is applied. As illustrated in Figures 7 and 8, template 12 produces converging and diverging vectors that smooth surface morphology by contracting (valleys) and distracting (peaks) the collagen matrix in a soft tissue structure. Diverging vectors on the peaks lengthen the collagen matrix while converging vectors in the valleys contract

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and compact the collagen matrix. The overall result is the smoothing of an irregular skin surface.

Apparatus 10 may also be used to treat wrinkling of the skin. The treatment of skin wrinkles is shown in Figure 9. In a skin wrinkle the vectors are directed perpendicular to the troughs and ridges of this contour deformity. Diverging vectors at the ridges of the skin converge in the trough of the wrinkle to smooth the surface morphology. The collagen matrix is distracted or extended at the ridges and contracted in the valleys. The overall result is the smoothing of the wrinkled skin surface.

Linear scars exhibit a similar morphology and can be remodeled with apparatus 10. Any surface irregularity with depressions and elevations will have vectors directed to the lowest point of the deformity. Prominent "pores" or acne scarring of the skin have a similar pattern to cellulite but on a smaller scale and can also be treated with apparatus 10. Clinically, the application of the mechanical force reduces the power required to remodel the matrix and diminishes cell necrosis of the skin surface as well as underlying soft tissue structures. Compression alters the extracellular fluid of the soft tissue structure (collagen) and exerts electrical impedance and thermal conductivity effects that allow delineation of a conduit-treatment interface of the collagen containing tissues. A deeper dermal interface will contract skin and exert three dimensional contour effects while a more superficial interface will smooth surface morphology.

In circumstances in which expansion of the skin envelope is needed, the combined application of heat and pressure is also required. For breast reconstruction, expansion of the skin envelope is typically achieved with each inflation of a subpectoral breast expander. Figures 10(a) and 10(b) illustrate an expander with an RF receiver electrode. A telescoping segment with an RF energy source is incorporated with access valve and is used to expand a nipple areolar donor site for Pectoralis "Peg" Procedure. The segmental expander can also be

used to prepare the recipient site for delayed autologous "Peg" Flap. The pressure that is exerted on the skin and the periprosthetic scar capsule is from the inside. In this application, vectors are directed outward. As an adjunct to this expansion process, a controlled thermal pad may be incorporated into a bra, as illustrated in
5 Figure 10(c), which can be applied to the inferior pole of the breast skin to promote lengthening of collagen fibril within the skin and underlying scar capsule around the expander. The bra may also function as an external conforming template 12 to achieve a specific breast shape. The net result is the creation of a more esthetic breast reconstruction with three dimensional characteristics of the
10 opposite breast. In a like manner, other garments can be utilized as external conforming templates for other anatomical body structures.

In Figure 10(d) a breast expander is partially expanded within the breast. In Figure 10(e), the expander is fully expanded within the breast.

Template 12 applies a mechanical force in combination with the delivery of
15 energy, with minimal cell necrosis to the skin surface and underlying soft tissue structure, to remodel collagen both esthetically and functionally. Template 12 can be in a variety of different forms including but not limited to a garment that is illustrated in Figure 11. Energy source 22 can be directly incorporated into the fabric of a tight fitting garment or inserted as a heating/RF pad into a pocket of the
20 garment. Another example of a garment is a tight fitting bra that extends over the arm and waistline with zone control that provides contraction of the skin of the breast, arms, and waistline to a variable amount to create a desired three-dimensional figure. Functional remodeling of collagen containing structures include a variety of different applications for aesthetic remodeling.

25 As shown in Figures 12(a) and 12(b), template 12 can be a garment positioned over the nose, a garment positioned around the ear, and the like.

Template 12 can also be applied for functional purposes. Referring now to Figures 13 and 14, pre-term cervical dilation can be treated with a template 12

that is the impression "competent" cervix. The cervical template 12 create vectors that contract the circumference of the cervix. The incorporated energy delivery device 18 contracts the native matrix and induces scar collagen. The dilated cervical OS is tightened and the entire cervix is strengthened. Energy
5 delivery device 18 can be incorporated into template 12 which can be the cervical conformer and inserted as a vaginal obturator. It will be appreciated that template 12 can be utilized for other functional treatments.

In another embodiment, template 12 is a functional appliance that may be non conforming and can be separate or incorporated with the energy delivery
10 device 18. Orthodontic braces that are designed with energy delivery device 18 are used to remodel dental collagen and apply rotation and inclination vectors on the neck of the tooth which is devoid of enamel. In Figure 15(a) orthodontic braces are coupled to RF electrodes and associated power source. The orthodontic braces function as a non-conforming force application surface that
15 is coupled to incorporated RF electrodes. Figures 15(b) and 15(c) illustrates a orthodontic appliance that is a conforming template 12 coupled to RF electrodes. As a consequence, orthodontic correction is more rapidly achieved than current modalities that employ only mechanical forces. Orthodontic correction can also be achieved with a conforming template 12 that is the
20 corrected impression of the patient's dentition.

For orthopedic applications, an external fixation device is used as a non conforming functional appliance. This appliance is used in tandem with an energy source device, including but not limited to RF electrodes, that remodels the collagen of the callus tissue. More accurate alignment of osteotomy and
25 fracture sites are possible with either a conforming or nonconforming brace that is used in tandem or is directly incorporated into energy delivery device 18. Improved range of motion of contracted joints and correction of postural (spinal) deformities can be achieved with this combined approach.

The ability to remodel soft tissue in anatomical structures other than skin is dependent upon the presence of preexisting native collagen. Induction of scar collagen is performed in tissue devoid or deficient of native collagen. Template 12 can be used to remodel the subcutaneous fat of hips and thighs in addition to the tightening of the skin envelope. The convolutions of the ear cartilage can be altered to correct a congenital prominence. The nasal tip can be conformed to a more esthetically pleasing contour without surgery.

Template 12 can be used with any modality that remodels collagen. In addition to RF (molecular) remodeling of collagen, cellular modalities that invoke the wound healing sequence can be combined with a conforming esthetic template. Thermal and chemical sources (glycolic acid) induce a low level inflammatory reaction of the skin. Scar collagen induction and fibroblastic (cellular) contraction are directed into converging and diverging vectors by a conformer that produces a smoother and tighter skin envelope. In addition to achieving a smoother and tighter integument, the texture of the skin is also improved with this remodeling process. Older or less compliant skin has a greater number of intermolecular crosslinks in the dermal collagen than younger skin. Scar collagen induction with cleavage of crosslinks will produce a softer and more compliant skin envelope.

Referring now to Figures 16 and 17, template 12 can be stationary or mobile. A hand held conforming template 12 that is mobile provides the practitioner with greater flexibility to remodel the collagen matrix. Pressure and impedance changes can serve as a guide for the manual application of template 12. A hand held template 12 with an incorporated energy source may be applied over a conductive garment that provides three dimensional conformance to the treatment area. Less accessible areas can be remodeled with this particular device. Template 12 of Figure 16 is made of a semi-solid material that conforms a lax skin envelope to an underlying soft tissue structure. The semi-solid material customized the creation of force application surface 14 and reduces the need for precise fabrication

of an esthetic template. Suitable semi-solid materials include soft plastics that are thermally and electrically conductive.

Controlled remodeling of collagen containing tissue requires an electromagnetic device that lengthens or contracts the matrix with a minimum of cell necrosis. Energy delivery device 18 can include a plurality of RF electrodes with or without insulation. The non-insulated sections of the RF electrodes collectively form template energy delivery surface 20. In a similar manner, microwave antennas, optical waveguides, ultrasound transducers and energy delivery or energy remove fluids are used to form template energy delivery surface 20. Individual electrodes and the like can be multiplexed and to provide selectable delivery of energy.

Template 12 delivers both electromagnetic energy and mechanical energy to the selected body structure. Suitable body structures include but are not limited to, hips, buttocks, thighs, calves, knees, angles, feet, perineum, the abdomen, chest, back flanks, waistline, legs, arms, legs, arms, wrists, upper arms, axilla, elbows, eyelids, face, neck, ears, nose, lips, checks, forehead, hands, breasts and the like.

A variety of different mechanical forces can be applied to tissue including but not limited to, (i) pressure, (ii) expansion, (iii) stretching, (iv) extension, (v) prolongation, or (vi) lengthening. The pressure force can be a positive pressure or a negative pressure. Positive pressure provides a compression of collagen containing tissue, with converging and diverging vectors, and negative pressure creates an extension of collagen containing tissue with converging and diverging vectors.

In various embodiments, energy delivery device 18 provides a controlled delivery of electromagnetic energy to the skin surface that does not exceed, 1,000 joules/cm², or 10 joules/sec/cm²; provides a controlled delivery of electromagnetic energy to the skin surface not exceeding 600 joules/cm² during a single treatment

session (during a twenty-four hour period), operates in an impedance range at the skin surface, not exceeding 200 joules/cm² during a single treatment session, or not exceeding 10 joules/sec/cm²; operates in an impedance range at the skin surface of, 70 ohms cm² measured at a frequency of 88 Hz to 40 Kohms cm² measured at a frequency of 10 KHz; provides a controlled delivery of electromagnetic energy to operate in a range of thermal conductivity at a skin surface of 0.21 to 0.60 k; operates in a range of compression force applied to the skin surface and/or the underlying soft tissue anatomical structure not exceeding 400 mmHg, not exceeding 300 mm, not exceeding 200 mmHg or not exceeding 100 mmHg.

Figure 18 illustrates a schematic block diagram of an analog embodiment of a specific impedance monitoring device 24 that can be used with apparatus 12 and be incorporated into a feedback control system. Impedance monitoring device 24 is used to control the delivery of electromagnetic and mechanical energy to the skin surface and underlying soft tissue structure to minimize, and even eliminate, cell necrosis as well as blistering of the skin surface. Impedance monitoring device 24 monitors other parameters including but not limited to, if there is an open circuit, short circuit or if voltage and current is supplied to the tissue for more than a predetermined maximum amount of time. Such conditions may indicate a problem with apparatus 12. When energy delivery device 18 is one or more RF electrodes, a generator 26 supplies RF energy to the energy delivery surface 20. Generator 26 is turned on by a user operated switch and provides a signal to controller 28 to turn on the energy. An output 30 of controller 28 is coupled to an analog switch 32. When output 30 provides an "RF on" signal to the switch 32 an oscillator 34 coupled to an analog multiplier 36 through switch 32, supplies a voltage of a known frequency to analog multiplier 36. An output of analog multiplier 36 is coupled to a driver 36 which is coupled to the input of an RF amplifier 40. An amplified RF signal is supplied by generator 26 to a circuit 42. Current and

voltage delivered to tissue is measured and an RMS current ("I sub RMS ") and an RMS voltage ("V sub RMS ") are determined. A voltage and current sensor 44 senses the current and voltage delivered to tissue. Voltage and current sensor 44 includes a low impedance current transformer 46 in series with generator 26 and a
5 high impedance voltage transformer 48 connected in parallel across generator 26. Current transformer 46 may have a 1:20 winding ratio and a 50 ohm resistor in parallel with a secondary of low impedance current transformer 46. Voltage transformer 48 may have a 20:1 winding ratio and a 1K ohm resistor in parallel with the secondary of low impedance current transformer 46.

10 The output of low impedance current transformer 46 is coupled to an RMS converter 50. RMS converter 50 converts a sensed current to a DC signal to provide output 52, representative of I sub RMS. The output of voltage transformer 48 is coupled to an RMS converter 54. RMS converter 54 converts the voltage signal into an DC signal and provide output 56, representative of V sub
15 RMS.

The measured impedance, Z, is then calculated from the measured I sub RMS and V sub RMS. Outputs 56, 54 of V sub RMS and I sub RMS are supplied to an analog divider 58 which divides the V sub RMS by the current I sub RMS to provide an output signal 60 representative of the measured impedance Z.

20 From the I sub RMS, V sub RMS and measured impedance Z, impedance monitoring circuit 24 determines whether, (i) a short circuit or open circuit condition exists, (ii) voltage and current has been delivered for an amount of time exceeding a predetermined maximum and (iii) whether controlled remodeling, contraction, tightening, smoothing and the like is complete.

25 A short circuit condition is determined by comparing measured impedance Z to a predetermined short circuit impedance threshold at or below which short circuit is likely to exist ("Z sub SC "). If the measured Z is at or below the Z sub SC, a short circuit signal is provided to

controller 28.

Impedance signal 60 is input to a short circuit detector 62 comprised of a comparator. A positive input 64 of the comparator is connected to a potentiometer 66 which sets the threshold impedance, $Z_{sub SC}$. When impedance
5 signal 60 causes the input at a negative input 68 of a comparator 70 to be lower than that at positive input 64, an "on" condition occurs at an output 72 of comparator 70. This condition is communicated to a logic controller which provides a preprogrammed response that can include turning off RF energy.

A current threshold detector 74 includes a potentiometer 76 coupled to a
10 negative input 78. Potentiometer 76 sets the $I_{sub thresh}$ level so that when a current is present, current detector 74 will indicate as such. The $I_{sub RMS}$ signal 86 is connected to a positive input 80 of current threshold detector 74. Thus, when the $I_{sub RMS}$ is greater than the value, $I_{sub thresh}$, set by the potentiometer 76, a positive voltage appears at an output of current threshold
15 detector 74.

Similarly, a voltage threshold detector 82 includes a potentiometer 84 connected to a negative input 86. Potentiometer 84 sets the voltage threshold at which threshold detector 82 registers a positive output, $V_{sub thresh}$, when a minimum voltage is present. The $V_{sub RMS}$ signal is input to a positive input 88
20 of the threshold detector 82. If $V_{sub RMS}$ exceeds $V_{sub thresh}$ set by potentiometer 84 a positive voltage appears at an output 90 of voltage threshold detector 82.

Output 90 of the voltage threshold detector 82 is also coupled to an AND gate 92 and the output of current threshold detector 74 is coupled to an inverted
25 input 94 of AND gate 92. AND gate 92 acts as an open circuit detector. When $V_{sub RMS}$ exceeds $V_{sub thresh}$ and where the $I_{sub RMS}$ does not exceed $I_{sub thresh}$, a logic 1 (not shown) will appear at an output 96 of AND gate 92.

indicating an open circuit. Output 96 of AND gate 92 is coupled to controller 28 to communicate the open circuit status.

5 The output of current threshold detector 74 is coupled to an OR gate 98 which is coupled to a timer 100. If $I_{\text{sub RMS}}$ exceeds $I_{\text{sub thresh}}$, the output of current threshold detector 74 will present a logic 1 to the OR gate 98 which will then turn on the timer 100.

Similarly output 90 of voltage threshold detector 82 is coupled to OR gate 98. If $V_{\text{sub thresh}}$ is exceeded by $V_{\text{sub RMS}}$, OR gate 98 will present a logic 1 at its output 102 and turn on timer 100. An output 104 of timer 100 is coupled to
10 controller 28. When timer 100 has been activated for an amount of time that exceeds a preset threshold time, $T_{\text{sub max}}$, output 104 will be a logic 1. Timer 100 is reset with a user activated switch that is coupled to the timer reset input 106, when apparatus 10 is reset.

A continuous comparison is made between Z and $f(Z_{\text{sub min}})$. It should
15 be noted here that $f(Z_{\text{sub min}})$ is continuously calculated as $f(Z)$ until a $Z_{\text{sub min}}$ is detected. The comparison is continuously made between Z and $f(Z)$ until $Z_{\text{sub min}}$ is determined.

If measured Z is less than or equal to the $Z_{\text{sub target}}$ then RF energy is continued to be supplied and steps described above are carried out until a signal
20 has been provided to controller 28 that there is an open circuit signal, short circuit signal or a time over signal. If the measured Z is greater than or is equal to " $Z_{\text{sub target}}$ " then a signal is provided to controller 28. It is noted that in this embodiment, Z has been inverted and shifted in order to accommodate $Z_{\text{sub min}}$ determination

25 A control device which controls an RF generator energy output based on load impedance. The load impedance is used to determine a preferred energy level, e.g., voltage, current or power level, based on a specific system load curve for generator 26, other power sources and/or application. The control device then

compares the actual energy level for measured impedance with the desired energy level and adjusts the generator output according to the difference between the two, i.e., preferably to minimize the difference between the two.

5 The specific load curve preferably reflects the voltage, current, power, for a range of impedance that will optimize performance of apparatus 10 for a variety of different procedures and anatomical body structures. The load curve may have various forms, for example, it may be continuous or may be stepped. The load curve may vary from power source to power source, or for different body structures and/or applications. In a one embodiment using apparatus 10, different
10 impedance ranges may be identified at which different energy requirements exist. Initially tissue impedance is in a lower range. In the lower ranges more current is required to provide enough power. A second, mid-range of impedances requires enough power to maintain the process. A third range of higher impedances may be required at the end of the process.

15 Referring now to Figures 19 through 22 a flow chart illustrates a method for carrying out a microprocessor controlled embodiment of the present invention. When the system is turned on (block 200), the variables including $Z_{\text{sub min}}$, $V_{\text{sub thresh}}$, $I_{\text{sub thresh}}$, time over, and $Z_{\text{sub initial}}$, are initialized (block 201). The system continues to look for the activation of the RF switch (block 202).
20 When the RF switch is turned on, the interrupts are set for RF Switch (block 203), for Short Circuit (block 204), and Open Circuit (block 205) so that when one of these interrupt conditions occur, the microprocessor automatically goes to the instructions associated with block 234.

25 After the interrupts are set, the timer is started (block 206). A sequence is run to check the RF amplifier health (block 207), e.g., to look for an Amplifier On signal or to check if certain voltages are in a suitable range. If the amplifier is operating properly, RF energy is turned on (blocks 208 and 209).

If the amplifier is not operating correctly, an RF Off request is made (blocks 209 and 210) and a Hardware Failure Alert flag is set (block 211). The system looks for a hardware failure flag (block 233). When the hardware failure is detected, the controller provides a hardware failure alert indication and shuts off.
5 (blocks 243 and 244).

If hardware failure is not indicated (block 233), then V sub rms and I sub rms is read (block 235) to determine if any voltage or current is being supplied by the system (block 236). When the system is first initialized, until the instruction to turn on energy in block 209 is reached, there should be no current or voltage. If
10 there is a voltage or current with the RF request off, then there is a hardware failure. A hardware failure alert is indicated and the program is stopped (blocks 243 and 244).

If RF energy is turned on (block 209), then the V sub rms and I sub rms are read and the impedance, Z, is calculated by dividing the V sub rms by the I sub rms. (block 212). The controller checks to see if the V sub enable and I sub enable
15 flags are set. (block 213). These flags are set when a minimum threshold voltage is present and a minimum threshold current is delivered through the electrodes of the device. (blocks 214, 215, 216, and 217).

If the V sub enable and I sub enable flags are set (213) the software looks
20 for a time over condition to determine if the device has been on for a period of time in excess of a maximum. If a time over condition is recognized, the timer flag is set, RF energy is turned off (blocks 218 and 219) and a hardware failure check is run (block 233).

After looking for a time over condition, the controller checks for a short
25 circuit or open circuit condition. If a short or open circuit exists, the corresponding short circuit or open circuit bit is set (block 220), RF energy is turned off (block 221), and a hardware failure check is run (block 233).

The controller checks again for V sub enable and I sub enable in block 222, before proceeding to the threshold determining portion of the circuit illustrated in Figure 8. If the voltage or current did not exceed V sub thresh or I sub thresh in blocks 214 and 216, the controller iterates the sequence beginning at block 212 for detecting time over, short circuit, open circuit, i.e., the coagulation complete detection enable. This enables the device to wait until enough current and voltage is delivered to the circuit to check for the coagulation complete condition.

If the V sub enable and I sub enable flags are set, the short circuit and open circuit bits are not set (block 220), and the time over condition does not yet exist (block 219), the measured impedance used to determine if coagulation is complete as follows.

The Z initial flag is set during the first iteration and Z sub min is initially assigned the measured impedance value (blocks 223-225). Initially, Z sub min is the same as the measured impedance and thus block 227 is bypassed at block 226. A calculation is made of $f(Z \text{ sub min})$ (block 228). As long as the measured impedance is less than the $f(Z \text{ sub min})$, the sequence is iterated (229, 231). In the next iteration of blocks 223-231, the newly measured impedance is compared to the previous measured impedance which has been assigned Z sub min (block 226). As long as the impedance is decreasing, Z sub min will be reassigned the new value of the measured impedance (blocks 226 and 227) and the steps repeated. When the measured impedance is greater than or equal to $f(Z \text{ sub min})$, i.e. the threshold impedance, the coagulation complete flag is set (block 230). If coagulation complete flag is set, the RF is turned off (block 232) and the hardware failure check is run.

If after the initial run through the program a hardware failure alert occurs (block 233, 236) or an interrupt occurs, the program determines the cause and indicates as such (blocks 233-242). The V sub rms and I sub rms are read, (block

235). If no current or voltage is being delivered to the system, the controller checks to see if the open circuit, short circuit or time over flags have been set (block 237). If so then a signal indicates which flags have been set, and the program is returned to start (blocks 240, 242). Similarly, the controller checks for the coagulation complete flag (block 239). If there was the coagulation complete flag has been set, it will be indicated for ten seconds (block 241). If not, it will be indicated as not complete (block 240) and the program will return to point at the start (block 242). Preferably the electrical components selected to carry out the steps of Figures 17 through 20 are adapted to provide a complete iteration of all the steps at least every 1/50 second.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

CLAIMS

- 1 1. An apparatus for modifying a skin surface or a soft tissue structure
2 underlying a skin surface, comprising:
3 a template including a mechanical force application surface configured to
4 apply pressure to the soft tissue structure; and
5 an energy delivery device coupled to the template, wherein the energy
6 delivery device is configured to deliver sufficient energy to the template and form a
7 template energy delivery surface.
- 1 2. The apparatus of claim 1, wherein the template energy delivery
2 surface is formed at an interior of the template.
- 1 3. The apparatus of claim 1, wherein the mechanical force application
2 surface is a pressure application surface that applies pressure to the soft tissue
3 structure.
- 1 4. The apparatus of claim 1, wherein the mechanical force application
2 surface is an compression application surface that creates an extension and
3 compression of the soft tissue structure.
- 1 5. The apparatus of claim 1, wherein application of the mechanical
2 force and delivery of the energy tightens the skin surface.
- 1 6. The apparatus of claim 1, wherein application of the mechanical
2 force and delivery of the energy smooths the skin surface.

1 7. The apparatus of claim 1, wherein application of the mechanical
2 force and delivery of the energy smooths the skin surface.

1 8. The apparatus of claim 1, wherein application of the mechanical
2 force and delivery of the energy to the skin surface improves a compliance of the
3 skin surface.

1 9. The apparatus of claim 1, wherein application of the mechanical
2 force and delivery of the energy to the skin surface improves a flexibility of the soft
3 tissue structure.

1 10. The apparatus of claim 1, wherein application of the mechanical
2 force and delivery of the energy to the skin surface provides cellular remodeling of
3 collagen in the soft tissue structure.

1 11. The apparatus of claim 1, wherein the soft tissue mechanical force
2 application surface is at least partially conforming to skin surface.

1 12. The apparatus of claim 1, wherein the soft tissue mechanical force
2 application surface applies a substantially even pressure to the soft tissue structure.

1 13. The apparatus of claim 1, wherein the soft tissue mechanical force
2 application surface supplies a variable pressure to the skin surface.

1 14. The apparatus of claim 13, wherein the variable pressure applied to
2 the skin surface applies a substantially even pressure to the soft tissue structure.

1 15. The apparatus of claim 1, wherein the template applies a mechanical
2 force to the soft tissue structure.

1 16. The apparatus of claim 15 wherein the mechanical force applied is
2 sufficient to achieve a smoothing of the skin surface.

1 17. The apparatus of claim 16 wherein the mechanical force applied is
2 less than the tensile strength of the collagen.

1 18. The apparatus of claim 15 wherein the mechanical force is sufficient
2 to create vectors that cleave collagen cross-links and remodels the collagen.

1 19. The apparatus of claim 15 wherein the energy delivery device
2 provides electromagnetic energy to the skin surface.

1 20. The apparatus of claim 1, wherein the energy delivery device and
2 the template are configured to remodel collagen in the soft tissue structure with
3 reduced cell necrosis.

1 21. The apparatus of claim 1, wherein the template is a garment.

1 22. The apparatus of claim 1, further comprising:
2 a sensor positioned at the template and configured to be coupled to an
3 energy source.

1 23. The apparatus of claim 22, further comprising:
2 a feedback control system coupled to the sensor and to the energy delivery
3 device.

1 24. The apparatus of claim 23, wherein the feedback control system
2 provides a controlled delivery of energy to the energy delivery device.

1 25. The apparatus of claim 23, wherein the feedback control system is
2 configured to minimize an ablation of the skin surface.

1 26. The apparatus of claim 22, wherein the sensor is a thermal sensor.

1 27. The apparatus of claim 22, wherein the sensor is an impedance
2 sensor.

1 28. The apparatus of claim 22, wherein the sensor is a hydration sensor.

1 29. The apparatus of claim 22, wherein the sensor is a thermal
2 conductivity sensor.

1 30. The apparatus of claim 1, wherein the soft tissue conformance
2 surface substantially conforms to a head structure.

1 31. The apparatus of claim 1, wherein the soft tissue conformance
2 surface substantially conforms to a neck structure.

1 32. The apparatus of claim 1, wherein the soft tissue conformance
2 surface substantially conforms to a trunk structure.

1 33. The apparatus of claim 1, wherein the soft tissue conformance
2 surface substantially conforms to a dental structure.

1 34. The apparatus of claim 1, wherein the soft tissue conformance
2 surface substantially conforms to a competent cervix.

1 35. The apparatus of claim 1, further comprising:
2 a reverse thermal gradient device coupled to the template.

1 36. The apparatus of claim 35, wherein the reverse thermal gradient
2 device is a cooling device.

1 37. The apparatus of claim 35, wherein the reverse thermal gradient
2 device is a closed loop cooling channel positioned in an interior of the template.

1 38. The apparatus of claim 35, wherein the reverse thermal gradient
2 device is a closed loop cooling channel positioned at the soft tissue mechanical
3 force application surface.

1 39. The apparatus of claim 1, wherein the soft tissue mechanical force
2 application surface has a size and a geometry configured to deliver sufficient
3 pressure to create a compressive force to collagen in the underlying soft tissue
4 structure.

1 40. The apparatus of claim 1, wherein the soft tissue mechanical force
2 application surface has a size and a geometry configured to deliver sufficient
3 pressure to create an extension force to collagen in the underlying soft tissue
4 structure.

1 41. The apparatus of claim 1, wherein the template is configured to
2 deliver sufficient electromagnetic energy and pressure to collagen in the underlying
3 soft tissue structure to cleave collagen cross-links and contract a longitudinal axis
4 of a collagen fibril.

1 42. The apparatus of claim 1, wherein the template is configured to
2 deliver sufficient thermal energy and pressure to collagen in the underlying soft
3 tissue structure to cleave collagen cross-links and extend a longitudinal axis of a
4 collagen fibril.

1 43. The apparatus of claim 1, wherein the template is configured to
2 deliver sufficient electromagnetic energy and pressure to collagen in the underlying
3 soft tissue structure to cleave collagen cross-links and shear a longitudinal axis of a
4 collagen fibril.

1 44. The apparatus of claim 1, wherein the template has a size and
2 geometry configured to direct converging and diverging mechanical forces to the
3 skin surface to smooth the skin surface and tighten the skin surface.

1 45. The apparatus of claim 1, wherein the template has a size and
2 geometry configured to direct converging and diverging mechanical forces to the
3 soft tissue structure to create a three-dimensional contouring of the soft tissue
4 structure.

1 46. The apparatus of claim 23, wherein the feedback control system
2 provides a controlled delivery of electromagnetic energy to the skin surface that
3 does not exceed 1,000 joules/cm².

1 47. The apparatus of claim 23, wherein the feedback control system
2 provides a controlled dose rate of electromagnetic energy to the skin surface of no
3 more than 10 joules/sec/cm².

1 48. The apparatus of claim 23, wherein the feedback control system
2 provides a controlled delivery of electromagnetic energy to a skin surface to
3 operate in an impedance range at the skin surface of 70 ohms cm² measured at a
4 frequency of 88 Hz to 40 Kohms cm² measured at a frequency of 10 KHz.

1 49. The apparatus of claim 23, wherein the feedback control system
2 adjusts a frequency of the electromagnetic energy to correspond to a selected
3 energy delivery dose rate at the skin surface.

1 50. The apparatus of claim 23, wherein the feedback control system
2 adjusts a frequency of the electromagnetic energy to correspond to a selected
3 temperature at the skin surface.

1 51. The apparatus of claim 23, wherein the feedback control system
2 provides a controlled delivery of electromagnetic energy to operate in a range of
3 thermal conductivity at a skin surface of 0.21 to 0.60 k.

1 52. The apparatus of claim 23, wherein the feedback control system
2 provides a controlled delivery of electromagnetic energy to operate in a range of
3 compression force applied to the soft tissue structure not exceeding 400 mmHg.

1 53. The apparatus of claim 23, wherein the energy delivery device is an
2 RF electrode and the feedback control system provides a controlled delivery of

3 electromagnetic energy to operate with a frequency modulation of 250 KHz to 4
4 MHz.

1 54. The apparatus of claim 23, wherein the energy delivery device is a
2 dielectric heating delivery device and the feedback control system provides a
3 controlled delivery of electromagnetic energy in the range of 4 MHz to 60 MHz.

1 55. The apparatus of claim 23, wherein the energy delivery device is a
2 microwave antenna and the feedback control system provides a controlled delivery
3 of electromagnetic energy in the range of 915 MHz to 2,450 MHz.

1 56. The apparatus of claim 23, wherein the feedback control system
2 comprises:
3 an energy control signal generator that generates an energy control signal
4 to control energy supplied from an energy source to the energy delivery device;
5 and
6 an impedance measurement circuitry coupled to said energy delivery
7 device and measure an impedance of a selected site at the skin surface.

1 57. The apparatus of claim 56, wherein the impedance measuring
2 circuitry determines a minimum impedance value to determine a target impedance
3 value as a function of the minimum impedance value and compares the measured
4 impedance values to the target impedance value and alter the control signal when
5 said measured impedance value exceeds the target impedance value.

1 58. The apparatus of claim 56, further comprising:

2 an energy source configured to supply energy to the energy delivery device,
3 wherein the energy source is responsive to the control signal to supply energy to
4 the energy delivery device.

1 59. The apparatus of claim 56, wherein the impedance measuring
2 circuitry comprises:
3 a first device for determining the minimum impedance value;
4 a target determining device coupled to the first device configured to
5 determine the target impedance value as a function of the minimum impedance
6 value; and
7 a first comparison device for comparing measured impedance values to the
8 target impedance value and generating a signal indicating whether the measured
9 impedance value exceeds the target impedance value.

1 60. The apparatus of claim 23, wherein the impedance
2 measurement circuitry includes a microprocessor controller.

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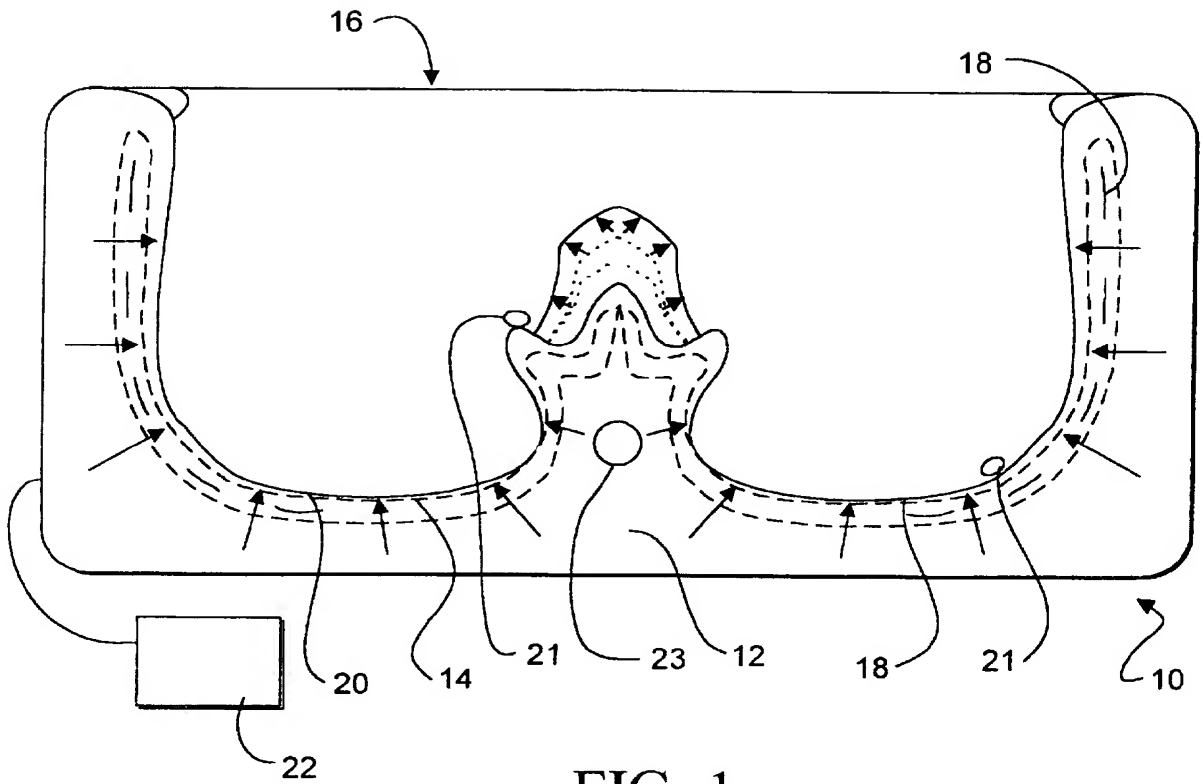


FIG. 1

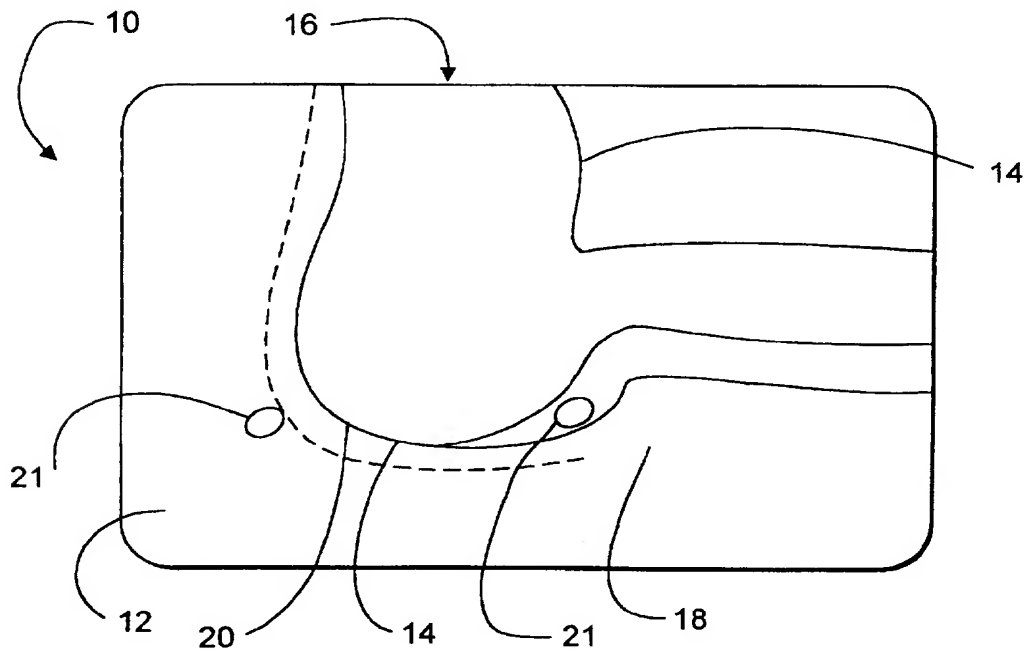


FIG. 2

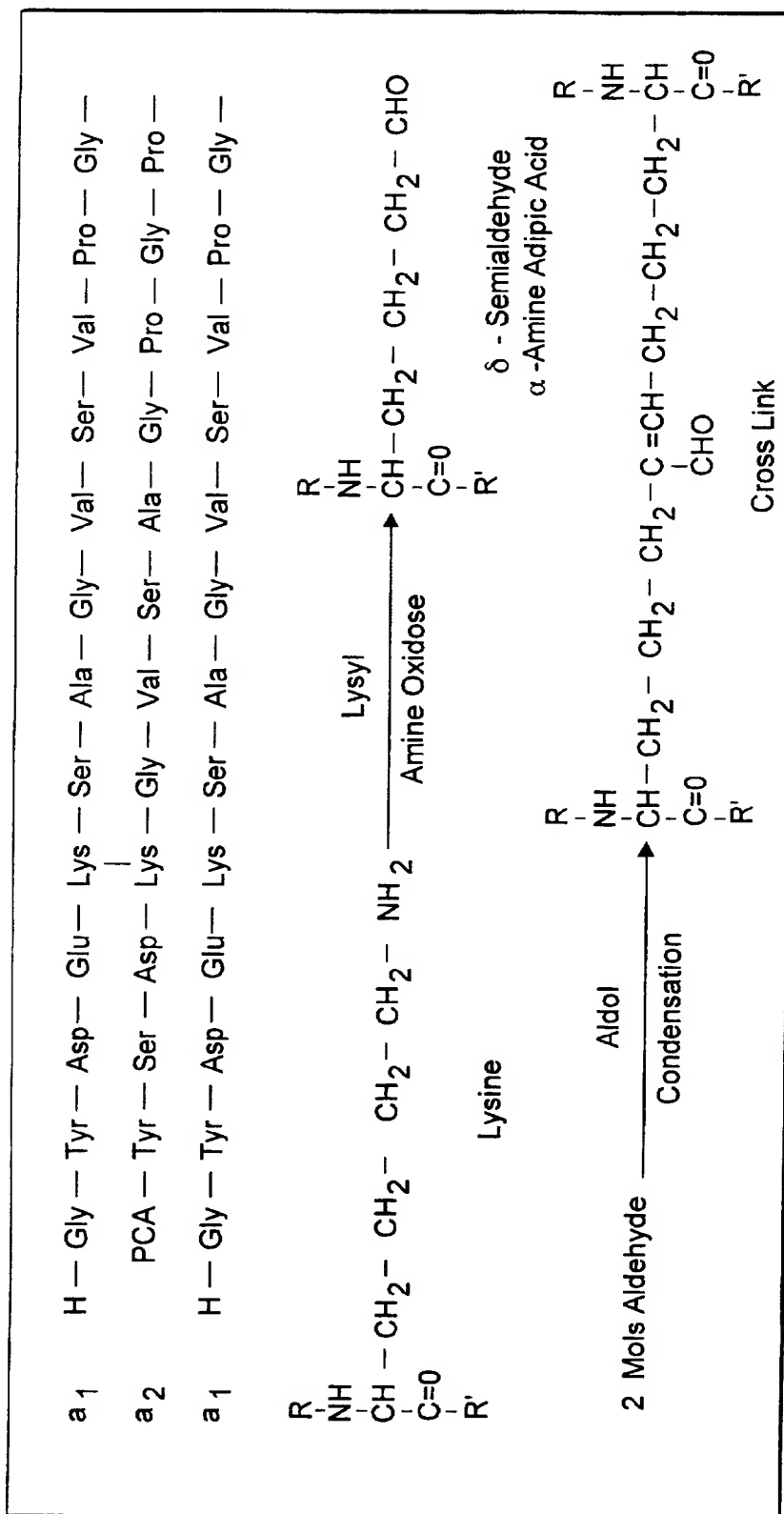


FIG. 3

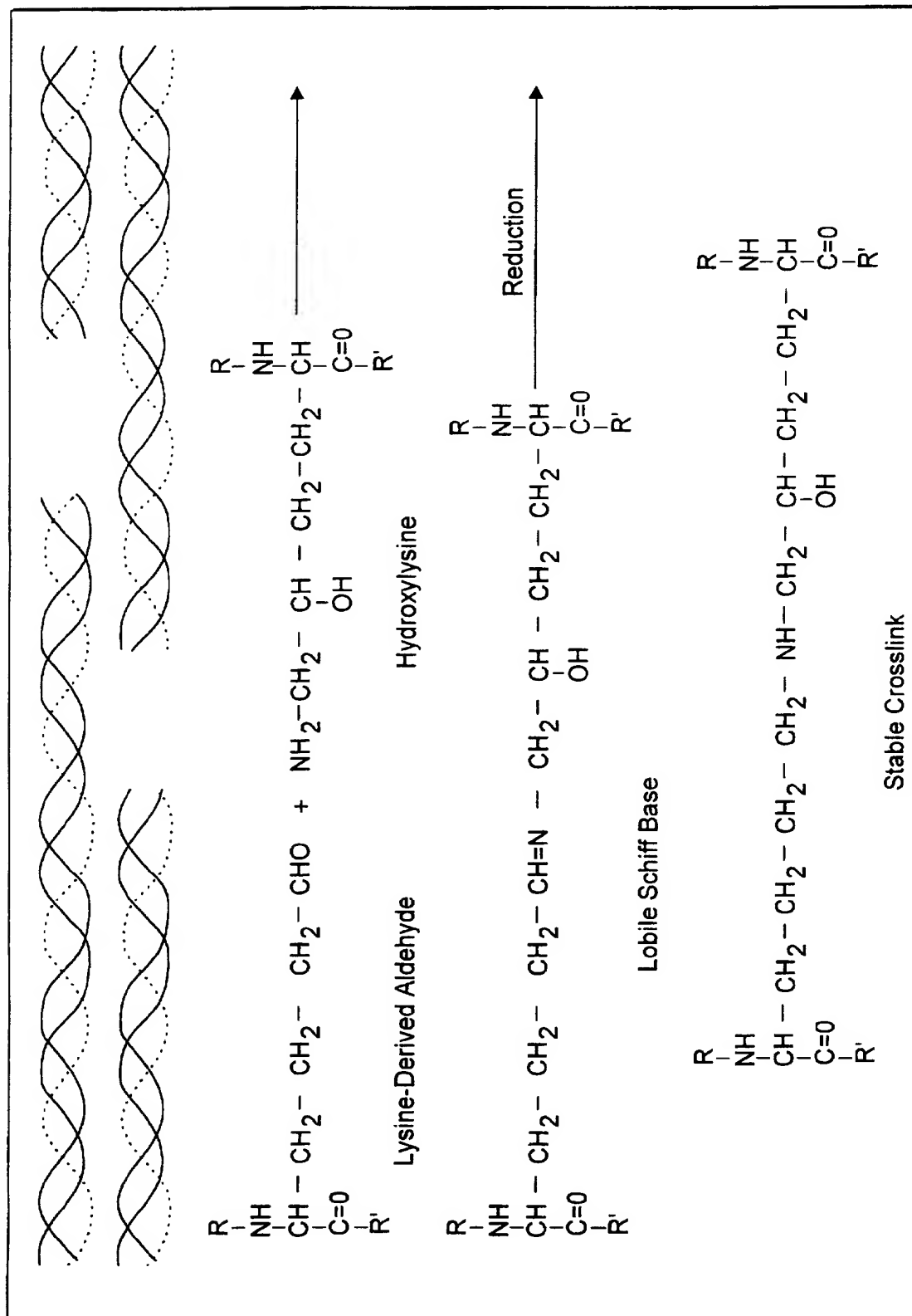


FIG. 4

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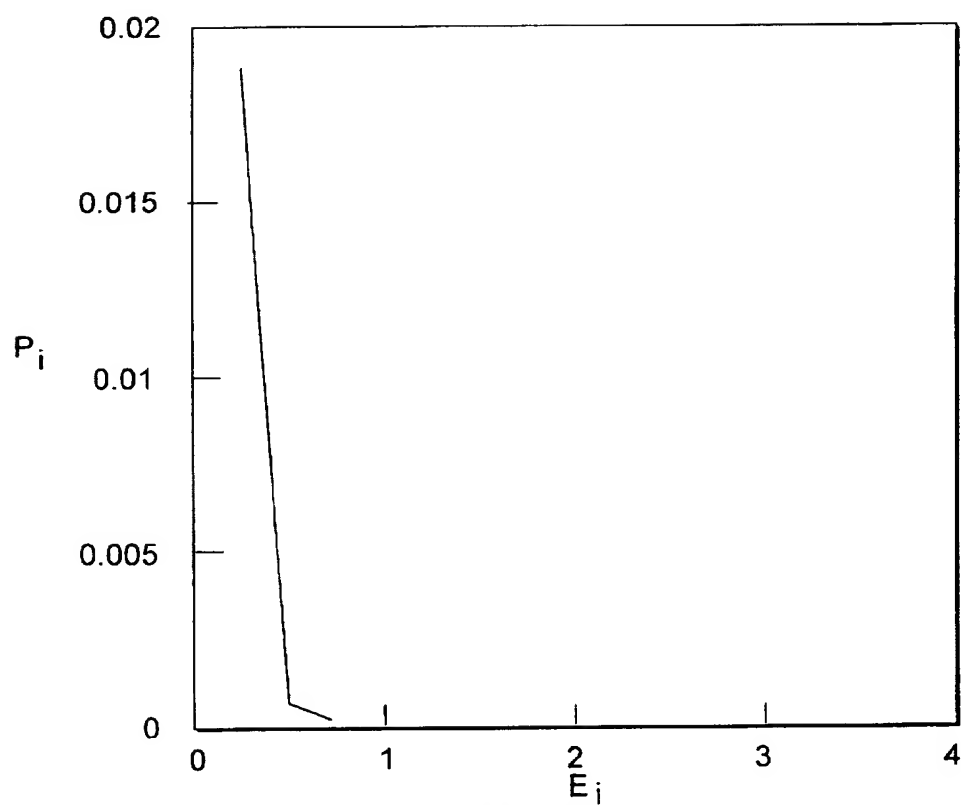


FIG. 5

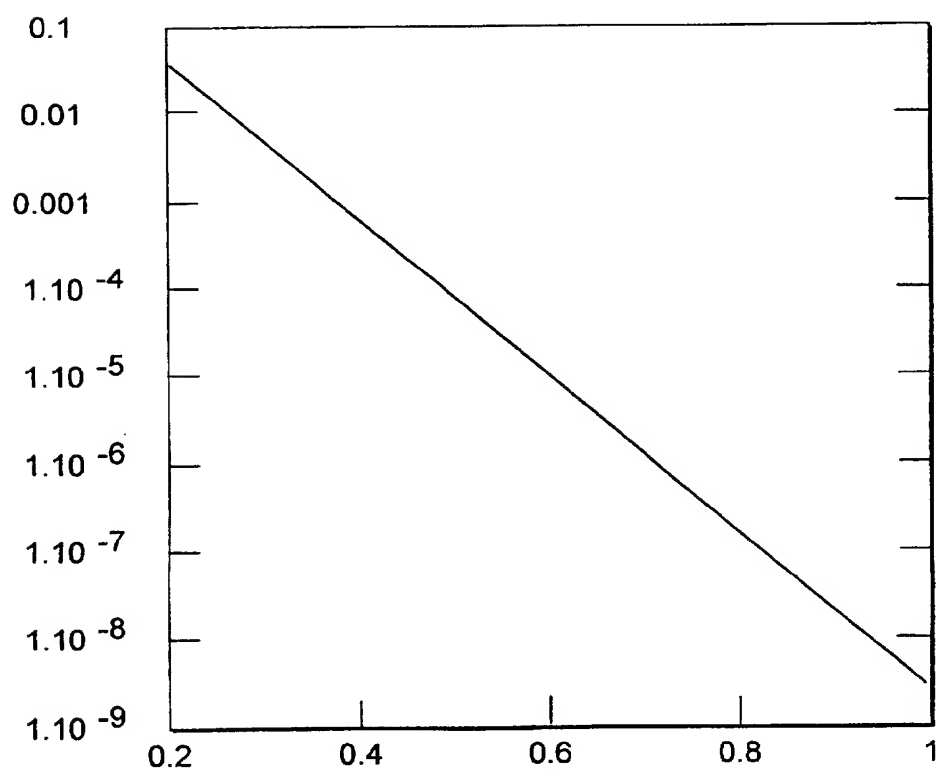


FIG. 6

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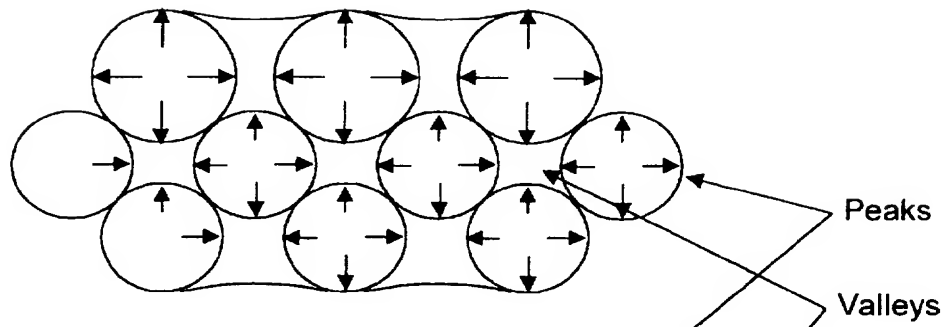


FIG. 7

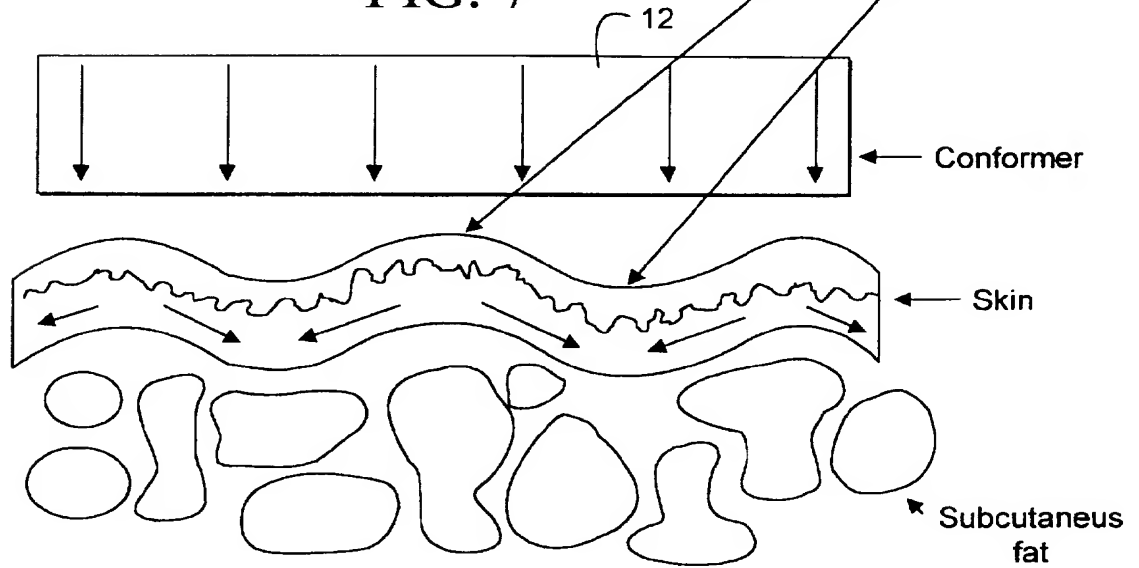


FIG. 8

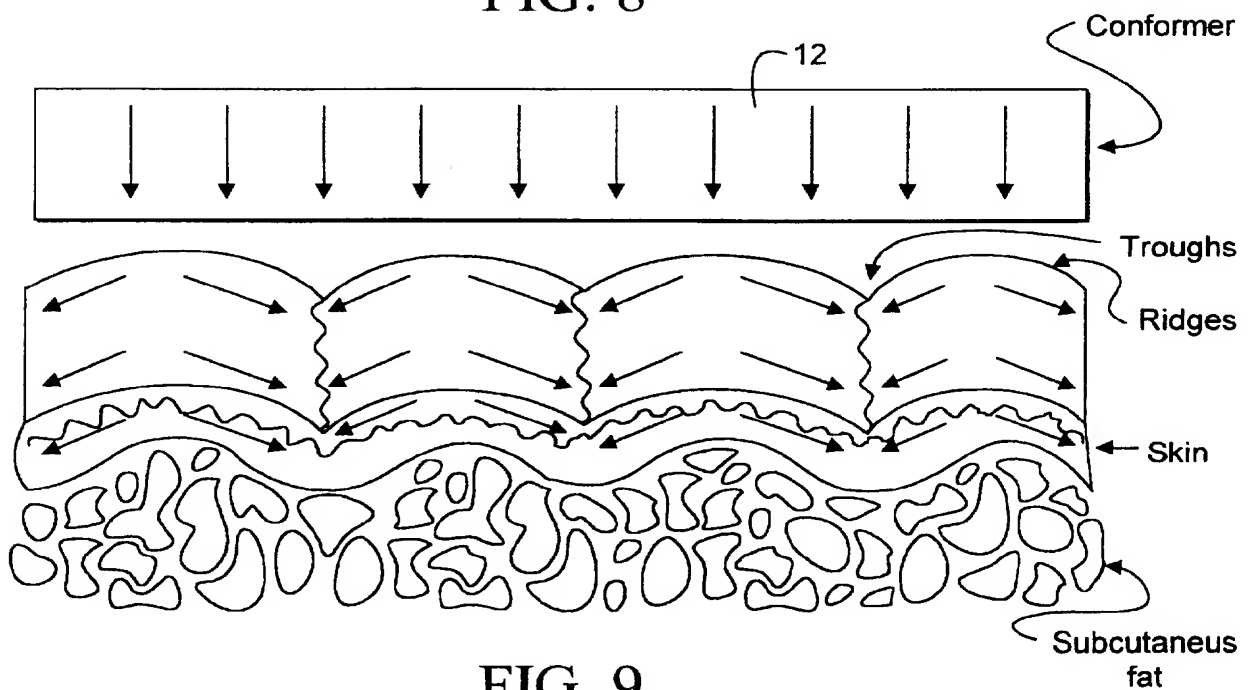


FIG. 9

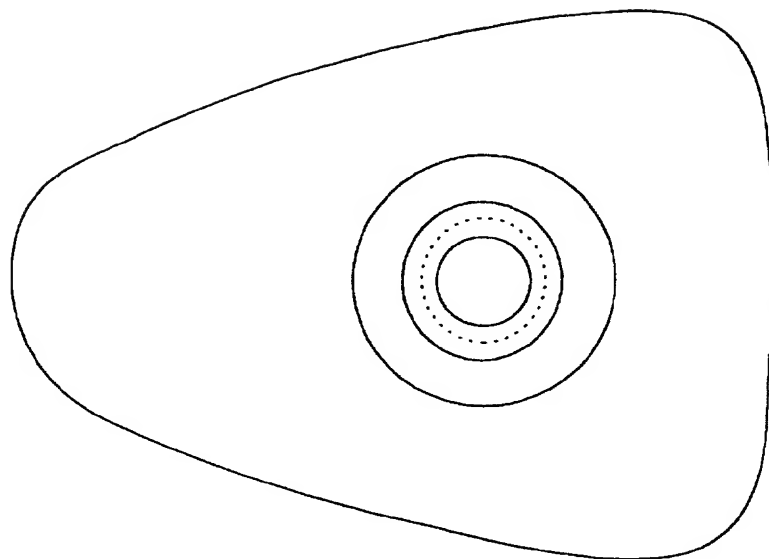


FIG. 10B

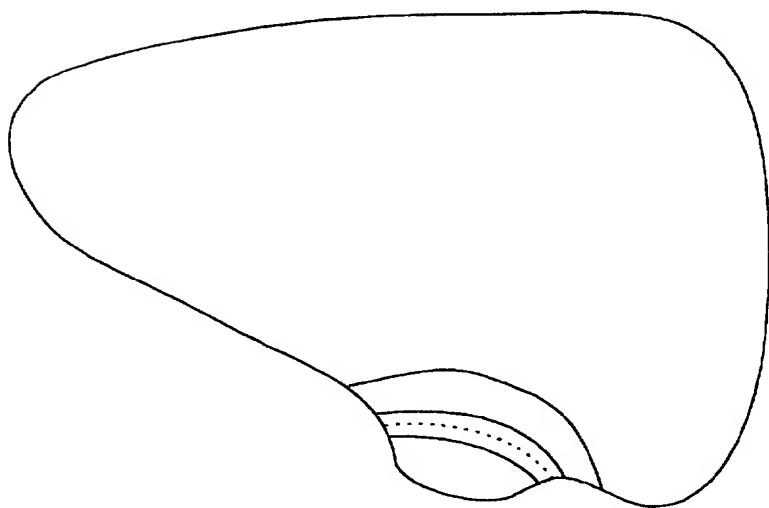


FIG. 10A

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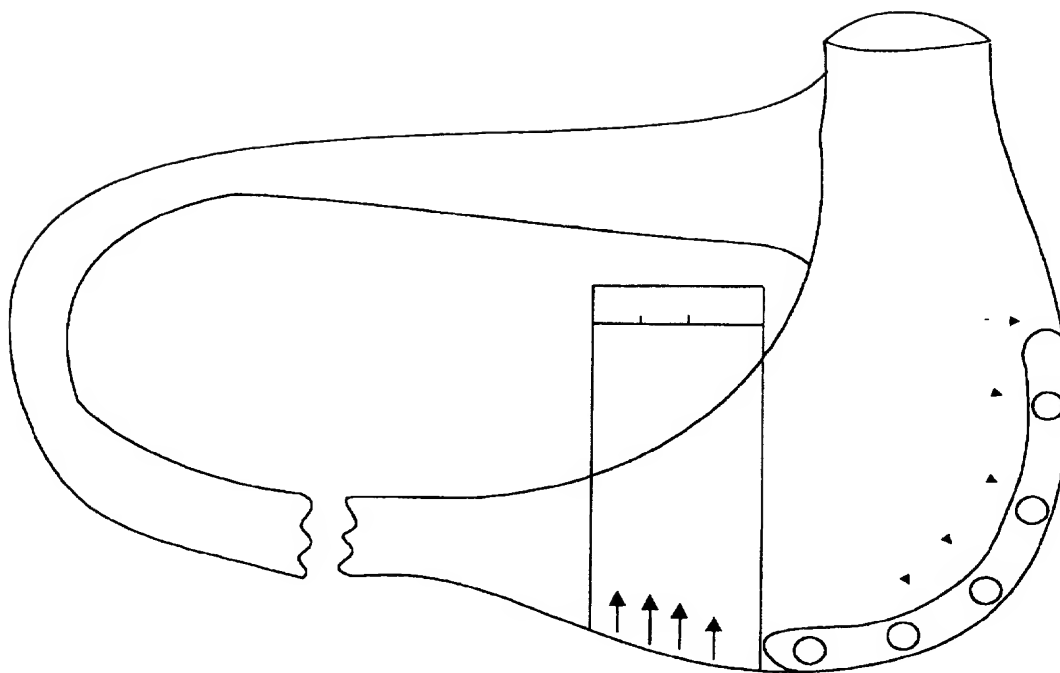


FIG. 10C

Fully Expanded

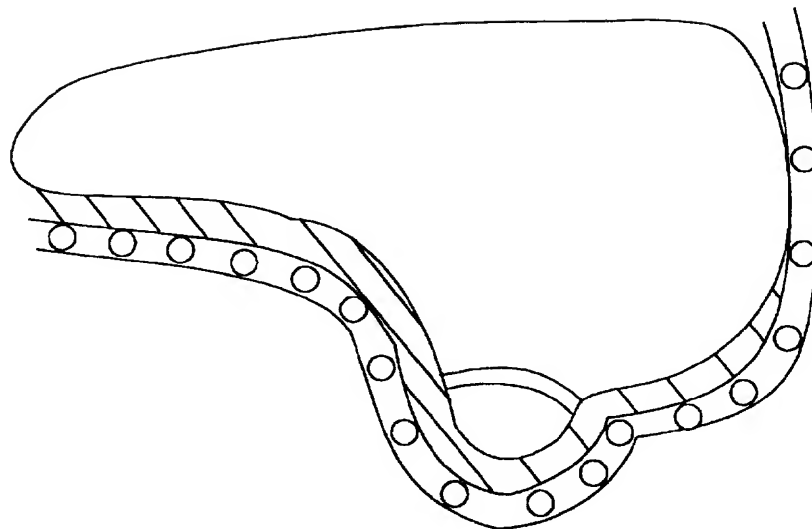


FIG. 10E

Partially Expanded

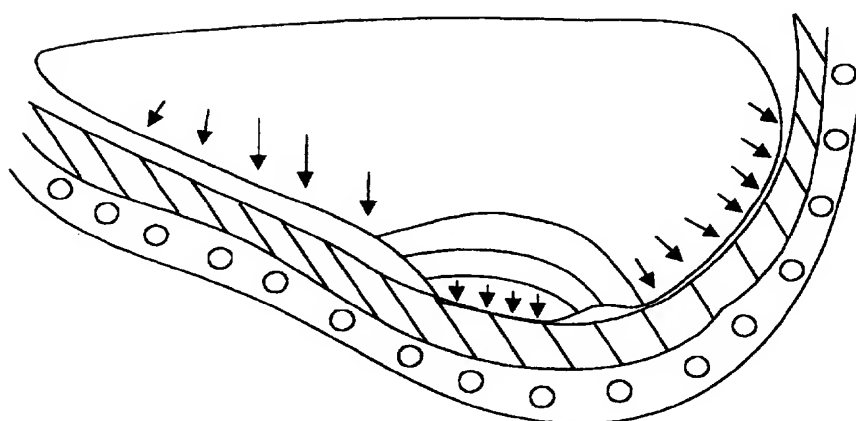


FIG. 10D

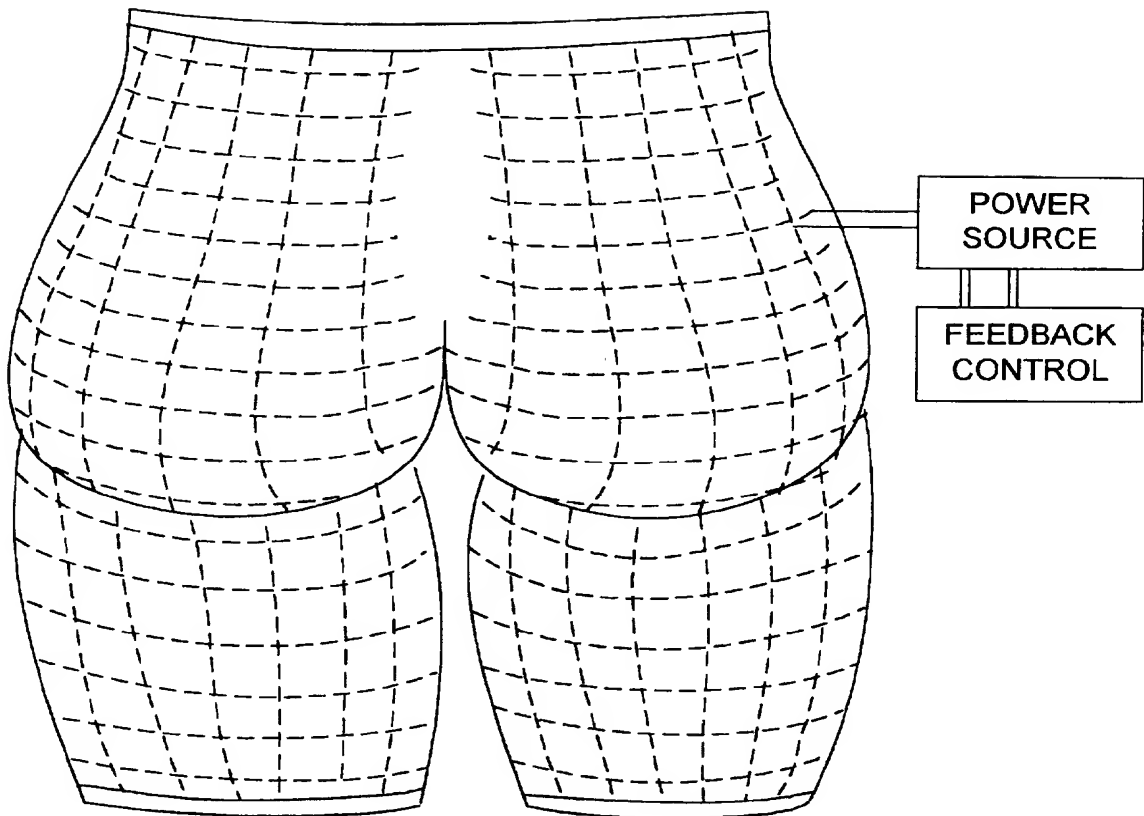


FIG. 11

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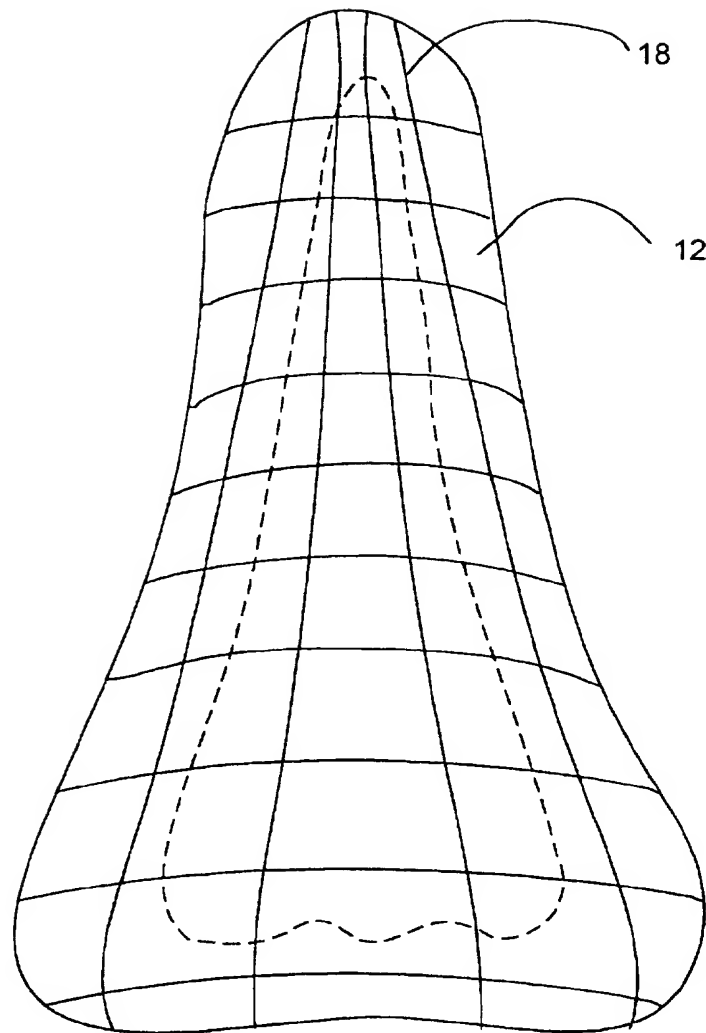


FIG. 12A

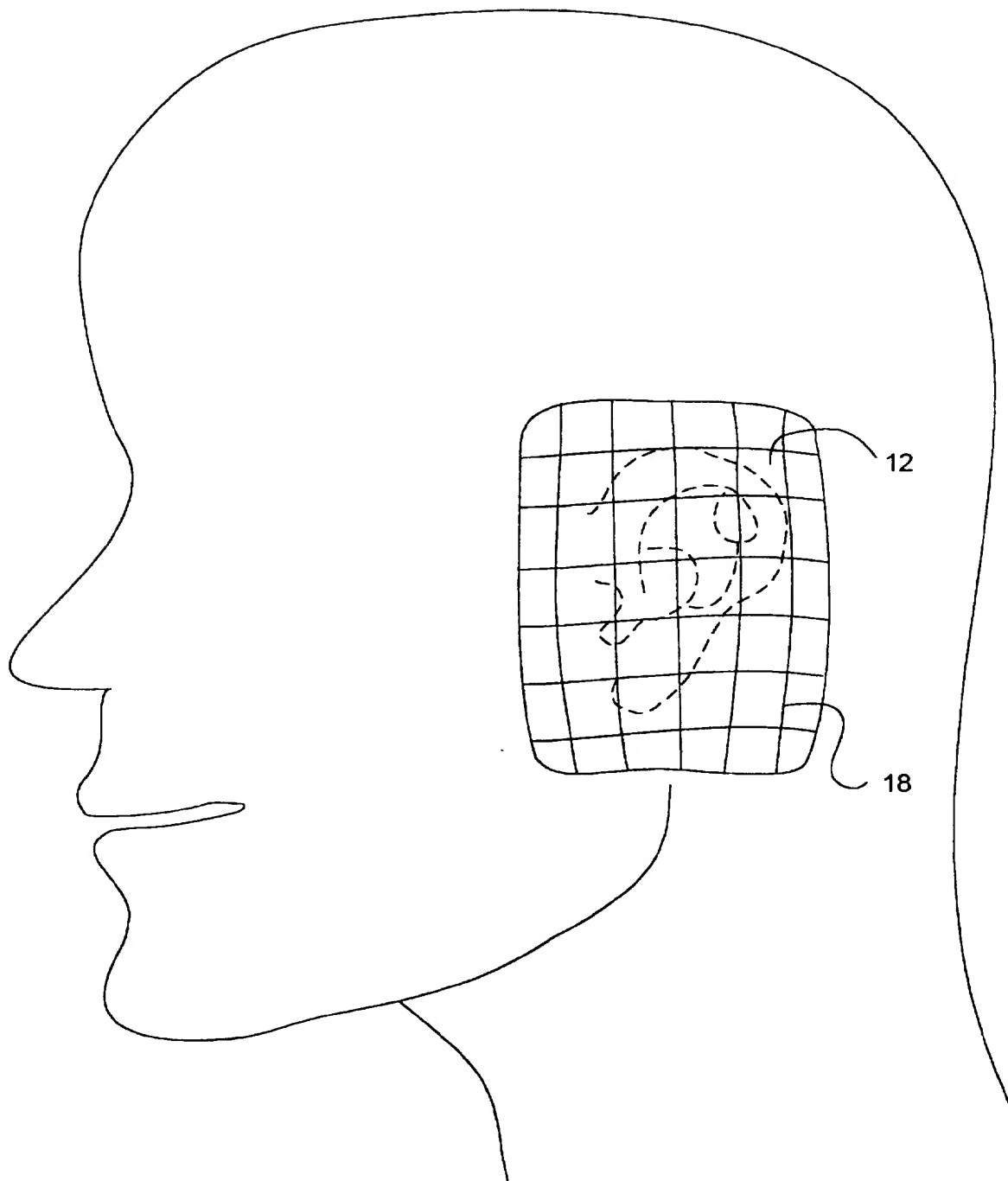


FIG. 12B

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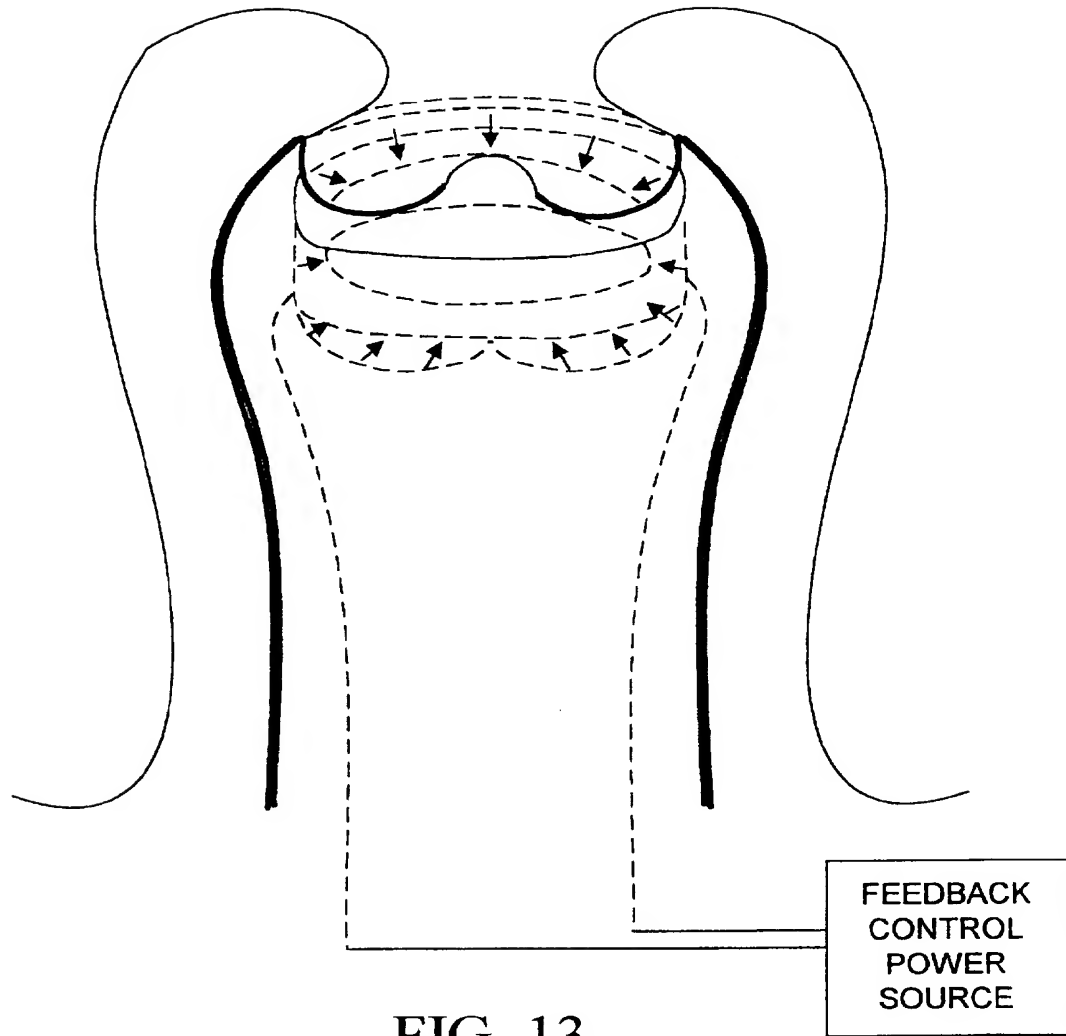


FIG. 13

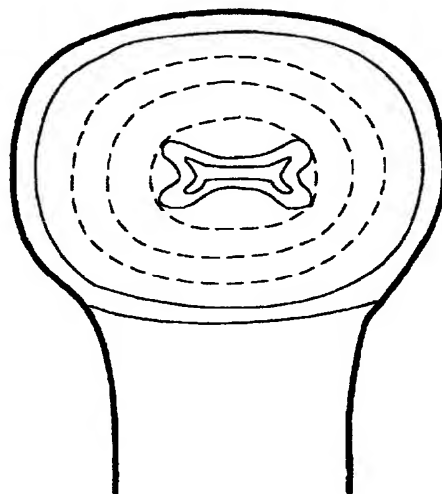


FIG. 14

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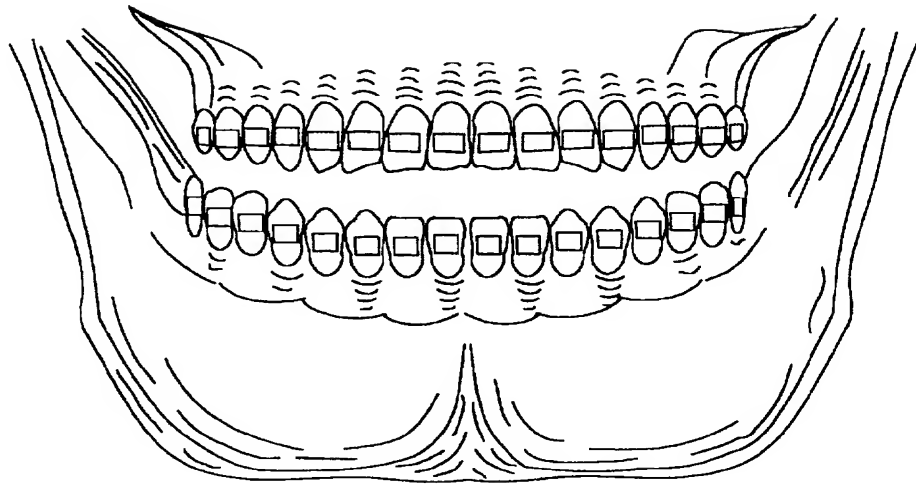


FIG. 15A

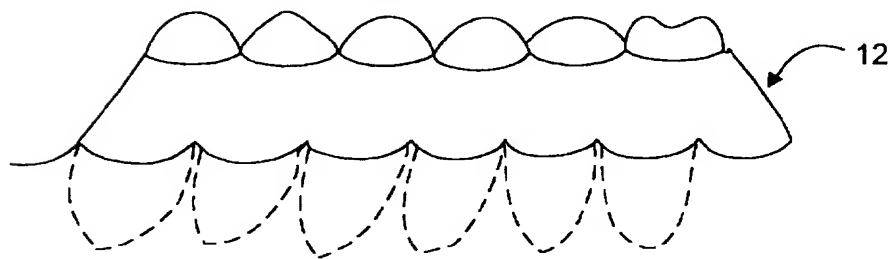


FIG. 15B

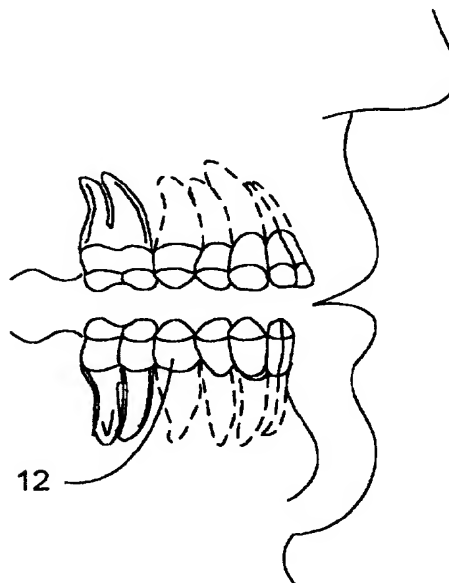


FIG. 15C

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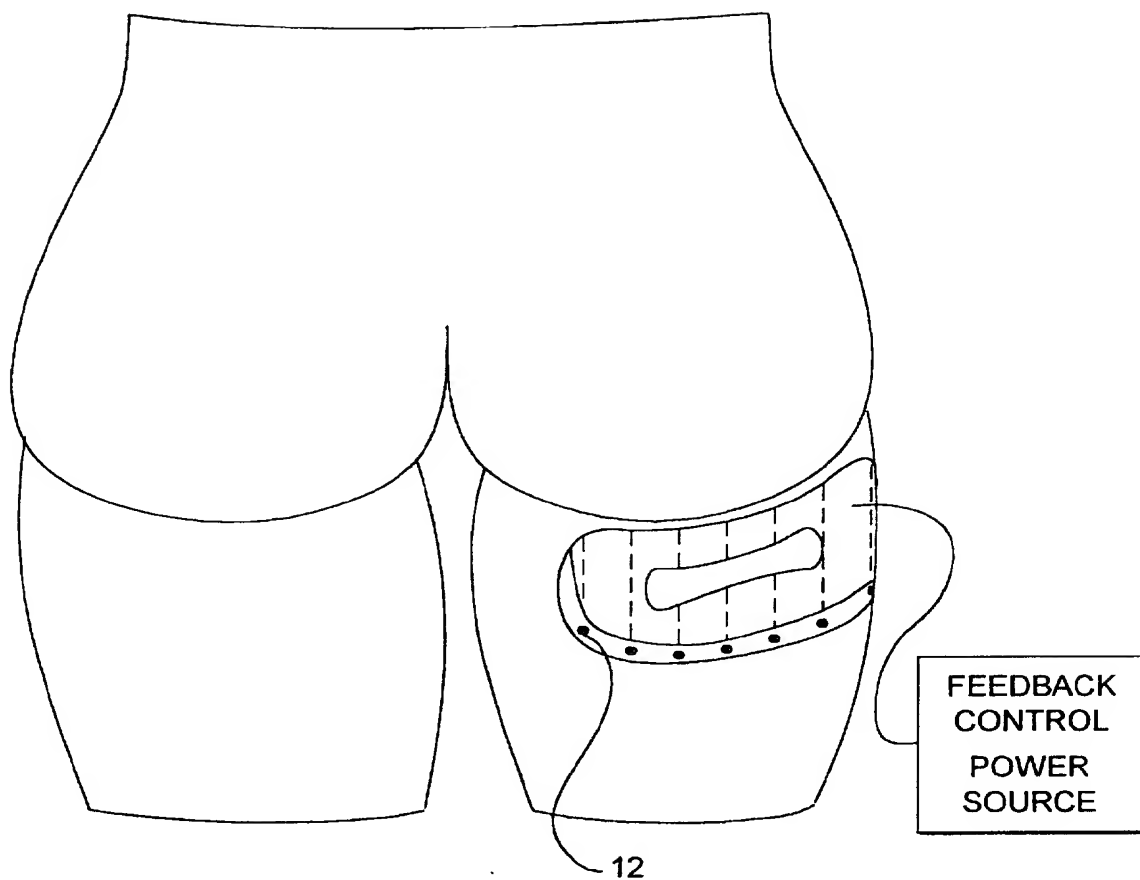


FIG. 16

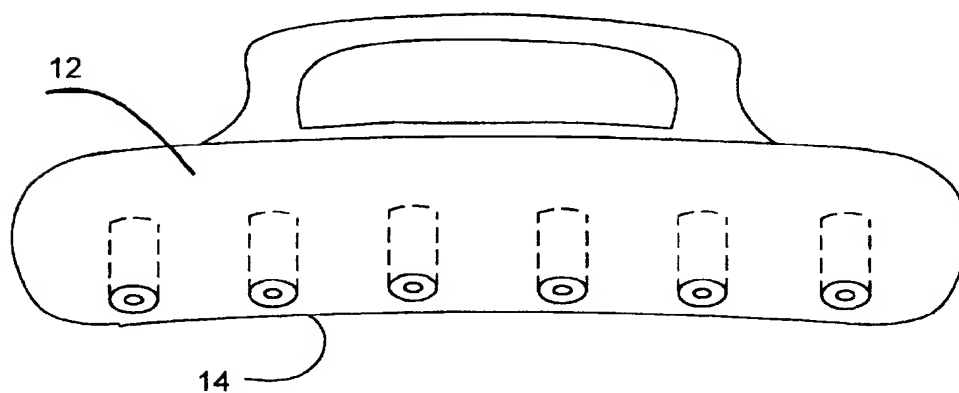
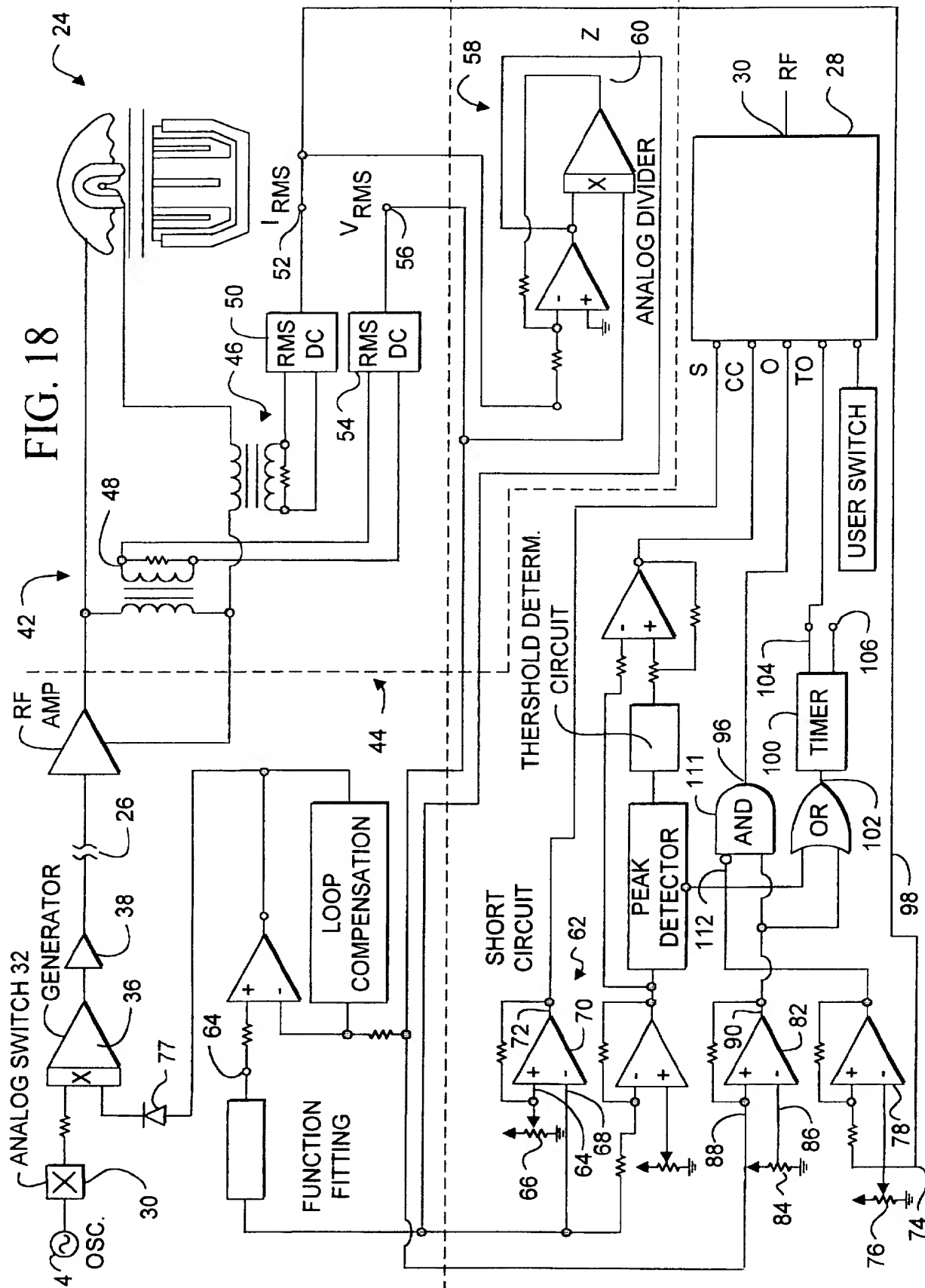


FIG. 17



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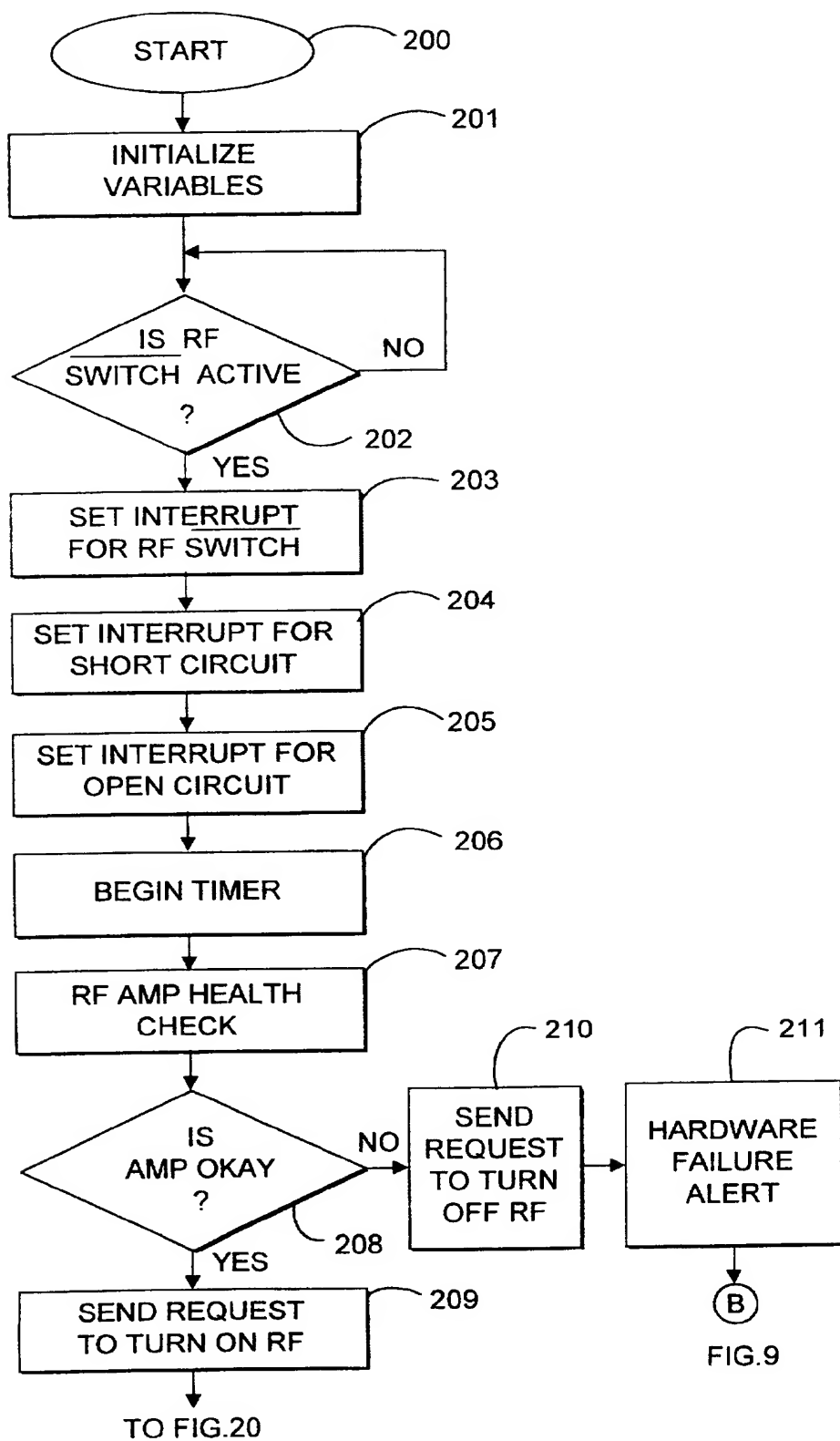


FIG. 19

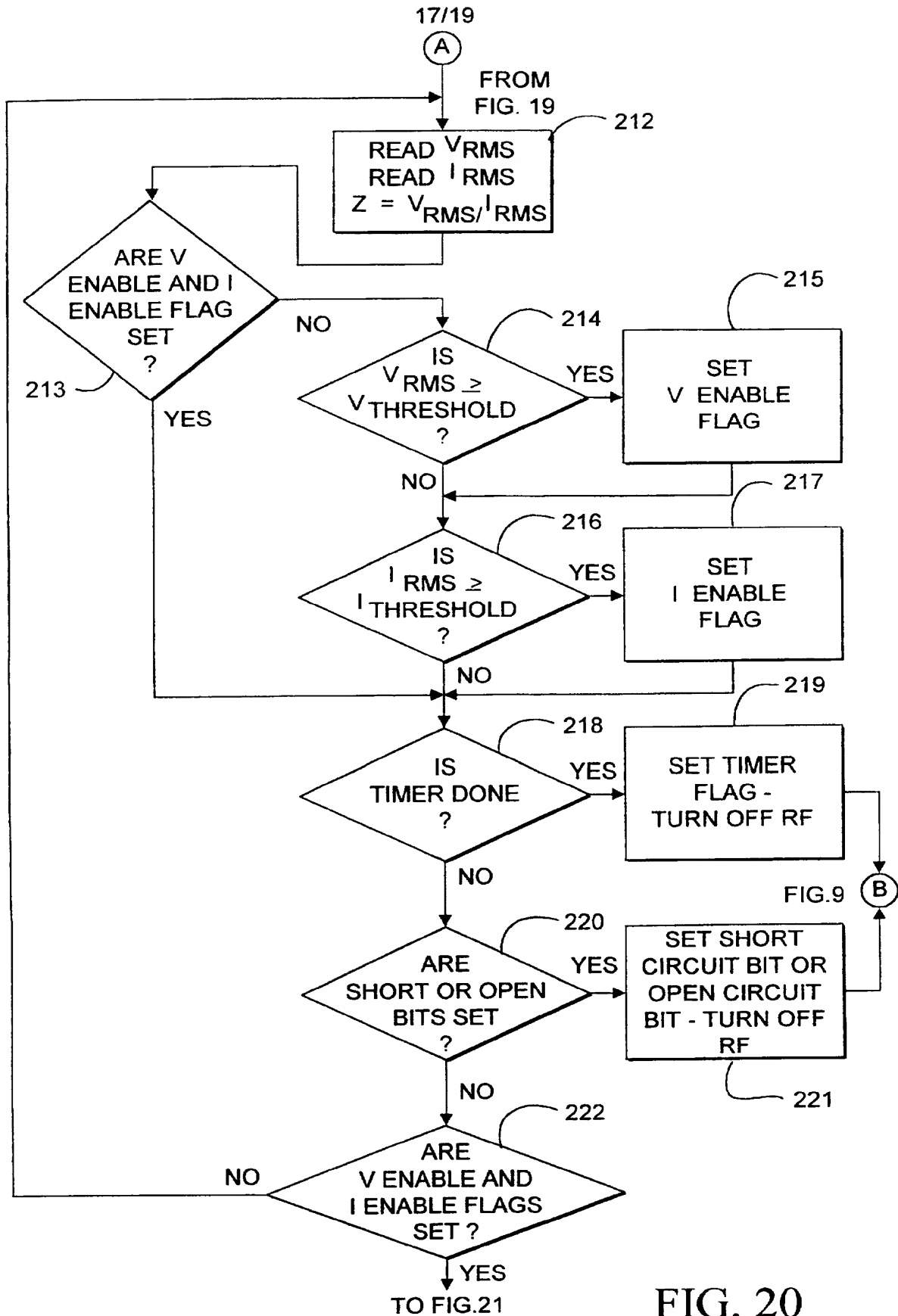


FIG. 20

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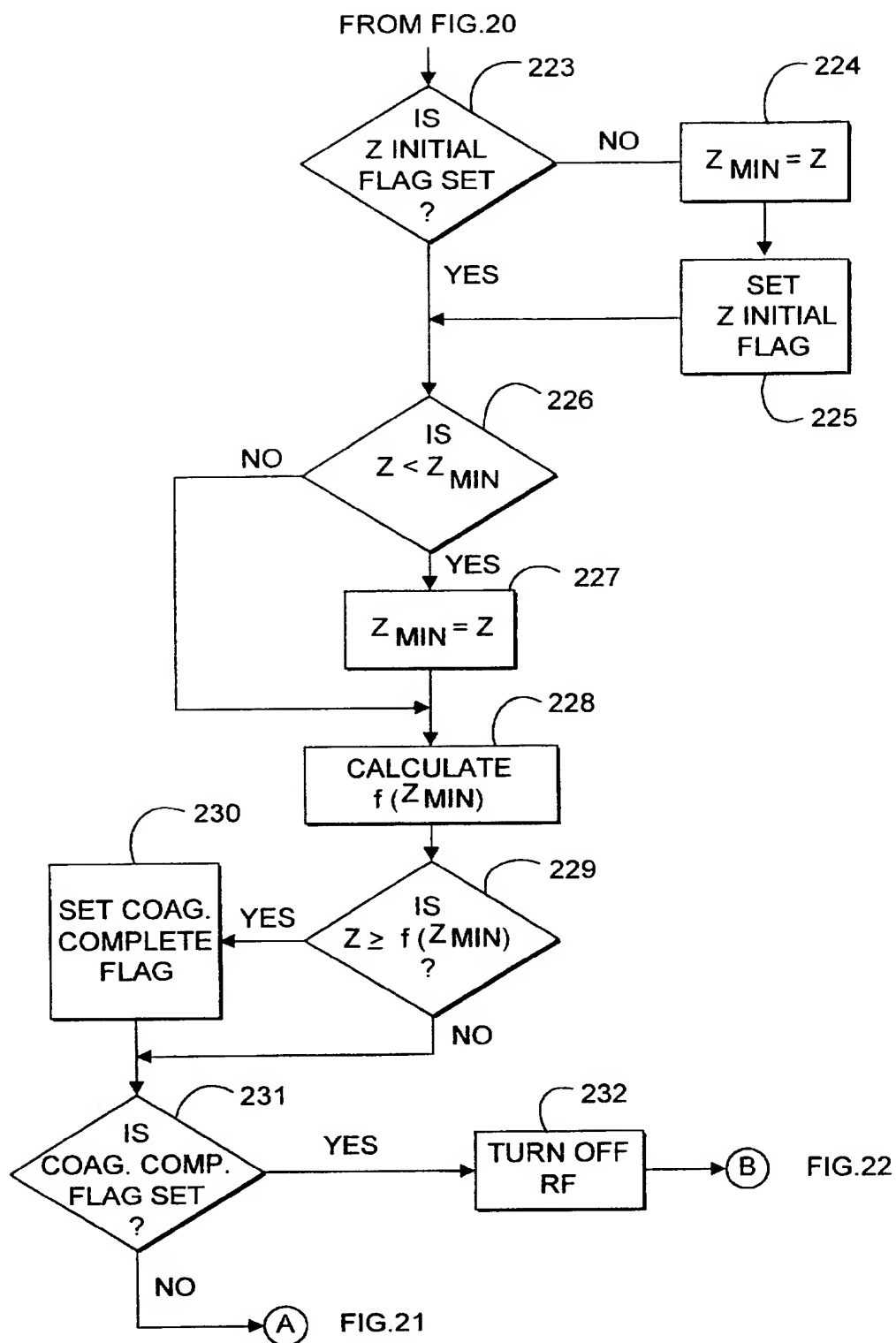


FIG. 21

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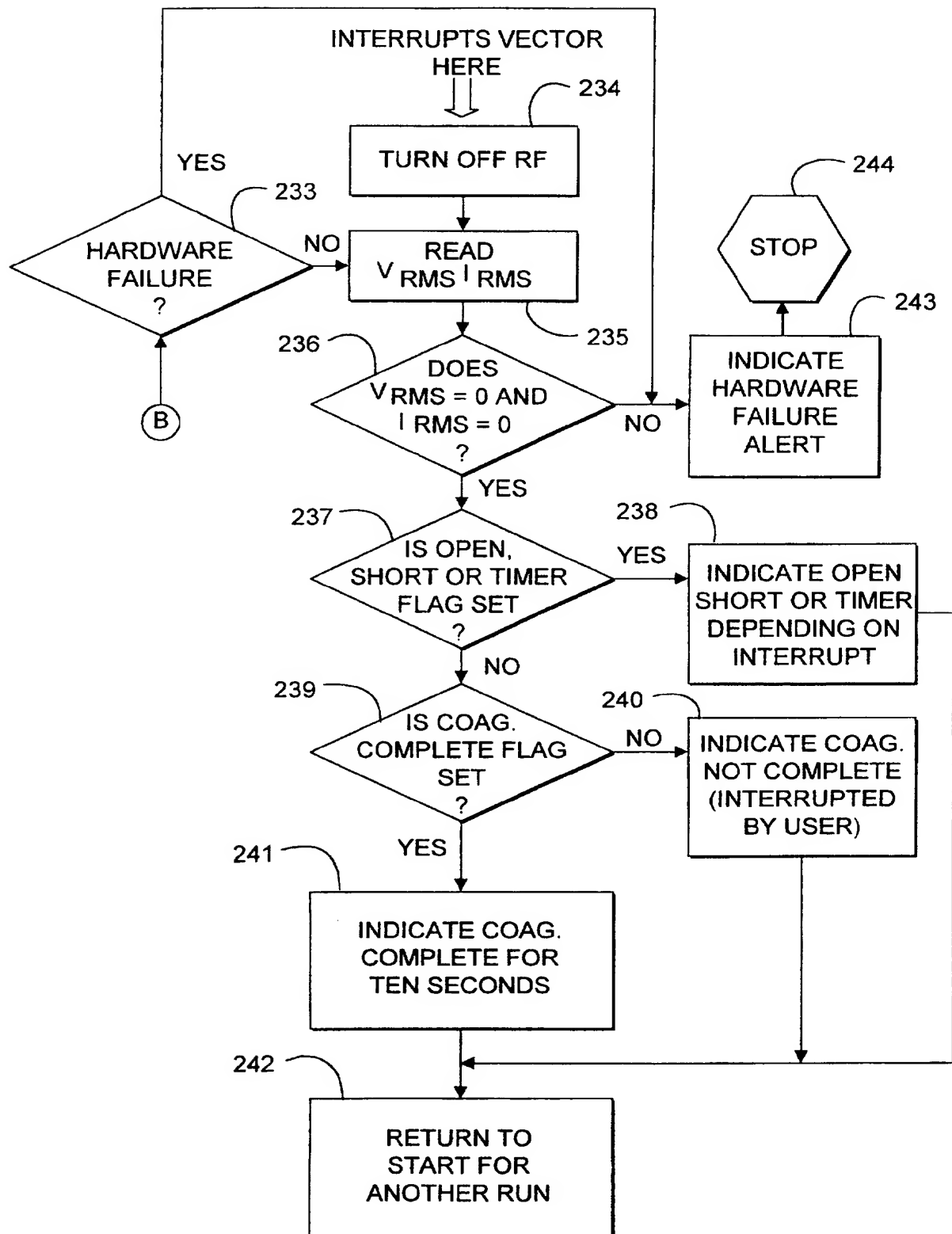


FIG. 22

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/13607

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61H7/00 A61N1/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61H A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 19 49 534 A (BAUCHE) 23 April 1970 see claim 1; figures 4,5 ----	1
X	GB 167 667 A (HAYASHIBARA) 4 June 1986 see abstract; figure 4 -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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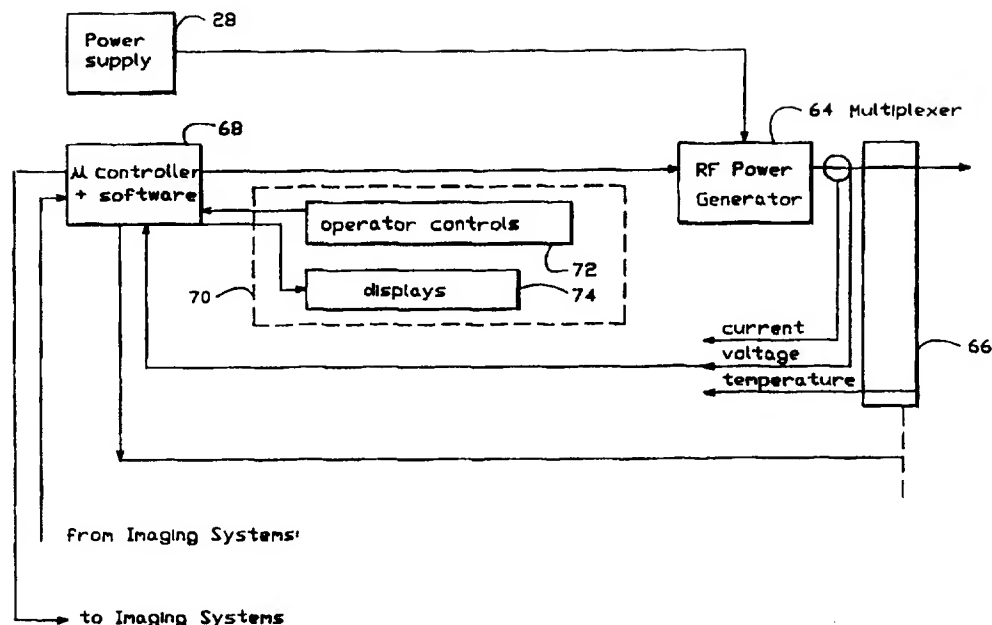
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(71)(72) Applicant and Inventor: KNOWLTON, Edward, W. [US/US]; 5478 Blackhawk Drive, Danville, CA 94506 (US).			
(74) Agent: DAVIS, Paul; Wilson, Sonsini, Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).			
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(54) Title: METHOD FOR TIGHTENING SKIN



(57) Abstract

A method for tightening skin provides for a modification of tissue impedance. An electromagnetic energy delivery device, with an energy delivery surface, is positioned with at least a portion of the energy delivery surface on a skin surface. Electromagnetic energy is delivered from the energy delivery surface through the skin surface, through the skin and to an underlying collagen containing tissue. An impedance of at least a portion of the skin or the underlying collagen containing tissue is modified. At least a portion of the collagen containing tissue is contracted and the surface of the skin is tightened.

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METHOD FOR TIGHTENING SKIN

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to a method for contracting collagen containing tissue and tightening skin, and more particularly, to a method for tightening skin by modifying the impedance and/or the thermal conductivity of tissues.

Description of Related Art

The human skin is composed of two elements: the epidermis and the underlying dermis. The epidermis serves as a biological barrier to the environment. In the basilar layer of the epidermis, pigment-forming cells called melanocytes are present. They are the main determinants of skin color.

The underlying dermis provides the main structural support of the skin. It is composed mainly of an extracellular protein called collagen. Collagen is produced by fibroblasts and exists as a triple helix with three polypeptide chains that are connected with heat labile and heat stable chemical bonds. When collagen is heated, alterations in the physical

properties of this protein occur at a characteristic temperature. This structural transition occurs in a manner analogous to the melting of a crystal. However, just as there is a "melting" temperature, there is a "shrinkage" temperature. The shrinkage of collagen is the basis for the technology and applications discussed in this presentation.

Soft tissue contraction is a biophysical phenomenon that occurs at cellular and molecular levels. Molecular contraction or denaturization of collagen involves the application of an energy source which results in the breaking of the heat labile bonds of the triple helix. As a result the longitudinal axis of the molecule contracts. This is essentially an immediate extracellular process, whereas cellular contraction requires a lag period for the migration and multiplication of fibroblasts into the wound as provided by the wound healing sequence. These cells differentiate into contractile myofibroblasts and are the source of cellular soft tissue contraction. Following cellular contraction, collagen is laid down as a static supporting matrix in the tightened soft tissue structure. Subsequent contraction can then be achieved by the molecular denaturization of collagen.

For example, tissue shrinkage with the denaturization of collagen occurs in second degree burns and is typically applied as a standard thermal gradient that is hotter on the surface and cooler in the underlying dermis. In these burn patients, cellular contraction and partial denaturization of dermal collagen results in a tightening effect on the skin. In contrast to the standard thermal gradient of a burn, the present invention provides a means to apply a reverse thermal gradient in which the skin's underlying collagen-containing layers are heated instead of the epidermis. Contraction of the skin and underlying soft tissue is possible without ablation or a second degree burn with its inherent blistering and

pigmentary irregularities. In a broader context, a reverse thermal gradient can also be described as a reverse gradient of collagen contraction in which collagen is preferentially contracted within a target tissue regardless of its relationship to a surface structure. Unwanted thermal effects and collagen contraction on adjacent soft tissue structures are avoided. Because collagen is found in tendon, bone, cartilage and all other connective tissue throughout the body, reverse thermal gradient contraction of collagen tissue can have many applications.

The selective induction of the basic wound healing process serves as the basis for the second major application of the present invention. In higher developed animal species, the wound healing response to injury involves an initial inflammatory process that subsequently leads to the deposition of scar tissue. The initial inflammatory response consists of the infiltration by white blood cells or leukocytes that dispose of cellular debris. Seventy-two hours later, proliferation of fibroblasts at the injured site occurs. These cells then produce scar collagen that functions as the main structural support of a healed wound. The deposition and subsequent remodeling of this nascent scar matrix provides the means to alter the consistency and geometry of soft tissue for both aesthetic and reconstructive purposes.

There exists an aesthetic need to contract skin without the scars, surgical risks or pigmentary side effects of commonly employed techniques. These techniques include surgical resection of skin and the use of lasers and chemical peels to burn the skin and achieve a tighter, more youthful appearance. Understandably, many patients are hesitant to subject themselves to these procedures, even though an overall aesthetic improvement is likely.

heat. Heat generated in the tissue around the electrode is influenced by several factors: distance from the electrode, RF current intensity and frequency, tissue impedance, shrinkage temperature (T_s), heat dissipation, and duration of application of the RF current. Manipulation of these factors will allow for a more precise delivery of RF-generated heat to a target tissue while preserving the integrity of the skin.

There is a further need to discriminate various soft tissue structures by altering their relative absorption of electromagnetic radiation. More specifically, the preferential delivery of thermal energy to a soft tissue will allow a variety of applications from ablation to thermal conduction. By altering the extra-cellular fluid content of a soft tissue in specific ways, the delivery of thermal energy to a target tissue is achieved with minimal damage to skin and adjacent soft tissue structures.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide a method for tightening skin by the use of RF or other energy sources, including ultrasound, to promote a thermal conduction rather than ablation of collagen containing tissue.

Another object of the invention is to provide a method for tightening skin using multiple port focusing separately or combined with other energy sources

A further object of the invention is to provide a method for tightening skin through the management of conduction/convection energy losses in the soft tissue system.

Still a further object of the invention is to provide a method for tightening skin by altering tissue impedance achieved through surface hydration to increase conductance, injection of conducting and resisting

Skin resection procedures are limited in their application due to inherent scars. With face-lift procedures, scars can be hidden around the contour of the ear, thus providing an acceptable trade-off between the surgical scar and the aesthetic improvement. Surgical resection of skin on the hips, thighs, arms, knees and legs, however, provides only a modest improvement with fairly unsightly scarring. In addition, patients must undergo a post-operative phase of healing that may be both painful and inconvenient. Other risk factors, such as bleeding and infection, may prolong healing.

Liposuction is effective at removing fat in some areas, however it does not tighten the skin envelope. Skin resurfacing techniques that secondarily tighten excess skin (such as laser and chemical peels) employ a "standard thermal gradient" that requires burning off the superficial skin as a second degree burn. The thermal effects of collagen contraction in the deeper dermis occur, but require a painful healing phase due to the second degree burn. These modalities depend upon re-epithelialization with cell migration from the skin appendages. This process of re-epithelialization is similar to the healing of any thermal burn and is more likely to cause pigmentary irregularities due to the destruction of melanocytes in the epidermis.

A need exists for the use of radio frequency (RF) energy to achieve a reverse thermal gradient, controlled contraction of collagen containing tissue and the tightening of skin. With RF energy, a high frequency alternating current (usually 100,000 to 500,000 Hz) flows from a parallel series of electrodes into tissue. Ionic agitation is produced in the tissue around the electrode as the ions attempt to follow the changes of direction of the alternating current. This agitation results in frictional heating so that the tissue, rather than the electrode itself, is the primary source of

fluids, invoking the inflammatory stage of the wound healing sequence to increase conduction and/or manipulation of collagen deposition and maturation.

Another object of the present invention is to provide a method for tightening skin by decreasing the shrinkage temperature of collagen by chemically altering molecular and fiber stability.

Yet another object of the present invention is to provide a method for tightening skin by modifying the thermal insulation characteristics of the skin to be more of a thermal conductor.

These and other objects of the invention are achieved in a method for tightening skin. An electromagnetic energy delivery device, with an energy delivery surface, is positioned with at least a portion of the energy delivery surface on a skin surface. Electromagnetic energy is delivered from the energy delivery surface through the skin surface, through the skin and to an underlying collagen containing tissue. An impedance of at least a portion of the skin or the underlying collagen containing tissue is modified. At least a portion of the collagen containing tissue is contracted and the surface of the skin is tightened.

In another embodiment, a thermal conductivity of the skin is modified to achieve skin tightening.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 is a perspective view of an apparatus for applying electromagnetic energy through the skin in order to cause a partial denaturization of collagen tissue, resulting in a tightening of the skin.

Figure 2 is a cross-sectional view of the skin and underlying tissue.

Figure 3 is a schematic representation of the collagen network.

Fig. 4 is a schematic diagram of an apparatus for applying electromagnetic energy to underlying subcutaneous layers or deeper soft tissue layers to create a desired contour effect by partially denaturing collagen tissue,

and without substantially modifying melanocytes and other epithelial cells in the epidermis.

Figure 5 is a block diagram of an RF system which can be utilized with the present invention.

5 Figure 6 is a block diagram of processing circuit of one embodiment of the invention.

DETAILED DESCRIPTION

10 For purposes of this disclosure, the following definitions apply:

Pre-Existing or Native

Collagen The protein substance of the white fibers
(collagenous fibers) of skin, tendon, bone,
cartilage, and all other connective tissue.

15

Thermal Induction of

Scar Collagen Deposition A non-ablative neosynthetic process of
collagen deposition as a reaction to
inflammation induced by thermal injury. The
20 resulting collagen is frequently referred to as
nascent, as opposed to pre-existing.

Standard Thermal

Gradient The thermal content of soft tissue that is
greater on the skin surface.

25

Reverse Thermal

Gradient A non-ablative remodeling effect upon either
pre-existing or nascent scar collagen.

5	Reverse Gradient of Collagen Contraction	A tissue environment in which collagen is preferentially contracted within a target tissue regardless of its relationship to adjacent or surface structures.
10	Contraction of Collagen	Morphological change that is produced by the cellular or molecular contraction of collagen-containing tissues.
	Tissue Impedance (TI)	The resistance in tissue to the flow of energy or current.
15	Tissue Conductance	The transmission of energy or current through tissue.
	Convection	The transfer of heat from one place to another by the movement of heated particles of gas or liquid.
20	Conduction	Process by which heat is transferred through matter, without transfer of the matter itself.
25	Fibroblast	The connective tissue cell that produces collagen and is the source of cellular contraction.
	Radiofrequency (RF)	

5	Energy	The segment of the electromagnetic spectrum (wavelengths 10^{-3} to 10^5 meters) that is released as thermal energy in tissue when ions are agitated by a high frequency alternating current.
	Current Density	The amount of current in tissue per square area.
10	Ultrasound	The use of high frequency sonic energy that is released as thermal energy in tissue due to the agitation of component ions.
15	Cellular Contraction	The morphological change of collagen containing tissue that is due to the contractile properties of the fibroblast.
20	Molecular Contraction	An extracellular process that is due to the non-ablative denaturization of the collagen molecule.

The present invention provides for the thermal shrinkage, or tightening of skin without the destruction of the overlying epidermis.

Skin tightening with a reverse thermal gradient (hereafter "RTG") contraction of collagen can correct areas such as the thighs, knees, arms, back and hips without unsightly scarring of standard techniques. Areas previously corrected by surgical procedures, such as face and neck lifts, could also be corrected without requiring surgery or the typical incisions around the ear. Elastosis, or stretching of the abdominal skin from

pregnancy, could be corrected without the long scar commonly associated with an abdominoplasty. Breast uplifts (mastopexies) would no longer require extensive incisions. It is believed that RTG contraction of collagen could be an effective, non-invasive alternative for the aesthetic treatment of these areas. RTG contraction of collagen could also be employed in areas not effectively treated by standard surgical techniques. Treatment of "cellulite" of the thighs and hips is one example.

Overall, the achievement of a RTG is the selective non-ablative contraction of collagen without thermal damage to surface and adjacent conducting tissues. Various modalities are available, (i) RF or other energy sources (ultrasound) that promote thermal conduction rather than ablation, (ii) multiple port focusing separately or combined with other energy sources, (iii) management of conduction/convection energy losses in the soft tissue system, (iv) alterations of tissue impedance (physical manipulation, surface hydration to increase conductance, injection of conducting and resisting fluids, invoking the inflammatory stage of the wound healing sequence to increase conduction, manipulation of collagen deposition and maturation, (v) decreasing the shrinkage temperature (T_s) of collagen by chemically altering molecular and fiber stability, and/or providing a mechanism to make the skin more of a thermal conductor than a thermal insulator.

Firming of soft tissue, such as the subcutaneous fat layer of the thighs, hips and breasts, with thermal induction of scar collagen deposition would provide a significant aesthetic benefit to patients by increasing the consistency of the soft tissue. Along with tightening of skin, the contour and consistency of subcutaneous tissue is enhanced without recourse to surgical procedures. As the device used does not require surgery, the method is more of an aesthetic treatment, rather than

an invasive operation. Other physicians (i.e. dermatologist or plastic surgeon) would initially administer treatments. Eventually, aestheticians could potentially be certified to administer these treatments, thereby greatly increasing access of their clients to this technology. Expansion of the marketplace into health spas as a franchise is certainly a possibility with these methods and medical devices.

Typically, the subcutaneous fat layers have loculations from fibrous septae that contain collagen. These fibrous septae can be contracted to tighten the soft tissue in areas such as the hips and thighs. Along with these extracellular effects of collagen, intracellular effects upon the fat cell, or lipocyte, by thermal induction will cause a net reduction of fat from the lipocyte which will achieve a net reduction in volume of the treated area. A second device (such as ultrasound focused at the appropriate level on the subcutaneous tissue) may be used in tandem with the RTG (RF device) heating pad to achieve liposculpture of the treated area.

A second broad application of RTG contraction of collagen involves the induction of scar collagen deposition. Thermal induction can incite the wound healing sequence of fibroblast proliferation with nascent scar deposition in soft tissues normally devoid or deficient of collagen. By introducing a carefully controlled thermal injury to structures that do not contain pre-existing collagen, it is possible to create scar collagen that can then be remodeled or contracted by subsequent treatments.

Another application of RTG is the treatment of sleep apnea, in which the soft palate in the back of the throat collapses and interferes with or obstructs breathing in sleeping individuals. Current treatments involve the surgical shortening of this structure, or laser treatments which employ a standard thermal gradient which burns the mucosa. The soft palate

contains a minimal amount of collagen. Thermal induction of scar collagen deposition on the soft palate followed by contraction to shorten the palate could relieve the functional airway obstruction. Furthermore, burning of the mucosa is avoided by employing a RTG instead of a
5 standard thermal gradient.

Additional medical applications of RTG contraction of collagen could include the treatment of unstable joints due to collateral ligament laxity. The thermal induction and deposition of scar collagen with subsequent contraction will reduce the hypermobility of these joints. In a
10 similar fashion, this technology can be applied in the treatment of unstable spinal column disorders, such as lumbar or cervical compression syndromes, and scoliosis that is often encountered in younger women. In this application, thermal induction of scar collagen deposition would be initiated in precise locations along the spine. Additional treatments would
15 then contract the scar collagen to counter the vectors of spinal deviation and increase the stability of the spine. In addition, the thermal induction of osteoblasts in the periosteum will result in callus (calcium matrix) formation. As callus contains a higher percentage of collagen than mature bone, subsequent remodeling with thermal contraction is possible.
20 Maturation of the remodeled callus with calcium matrix deposition will result in a stable bony fusion of treated areas.

Weaknesses of the abdominal wall, such as hernia or diastases rectus, could also be managed with the deposition of scar collagen that is subsequently contracted. Treatment of urinary incontinence and bladder
25 prolapse in women could be treated effectively with a device inserted into the vagina that would induce scar collagen deposition and contraction with RTG. Treatment of gastroesophageal reflux disease could be accomplished in a similar fashion with a device introduced

endoscopically. Aging of the skin involves thinning of the dermal layer from the progressive loss of collagen matrix. As a consequence, there is a reduction in the skin's turgor. Wrinkling of the skin occurs as a consequence of inadequate support of the epidermis. Therefore, treatment of wrinkles could be accomplished by combining a RTG contraction of dermal collagen with the induction of scar collagen deposition. Improved skin turgor is accomplished by first replenishing the collagen matrix that has been lost with aging. Following the induction and deposition of nascent scar collagen in the dermis, contraction of collagen with a RTG would correct wrinkling of the skin without resorting to "resurfacing" techniques that require the application of a standard thermal gradient burn to the skin. Prolonged healing and pigmentary irregularities would be avoided. The superficial papillary dermis is the treatment zone for this application.

A derivation of Ohm's law provides a means to alter and discriminate the biophysical properties of soft tissue. For electrical systems, $I = E/R$, where I is intensity of the current (measured in amperes), E is the energy potential (measured in volts), and R is the resistance (measured in ohms). For soft tissue systems, the current density delivered to a soft tissue target is inversely related to tissue impedance (TI). Most biological systems function as a combination of series and parallel circuits. If the tissue behaves as a series system, release of heat will occur in higher resistance target tissue. For electrical systems that function in parallel, delivery of current and energy may be shunted to low resistance areas.

Consequently, a higher power setting may be required for thermal release in this tissue system as higher resistance areas are bypassed. In these systems, high resistance areas may be protected and thermal effects

may occur in tissue in which impedance is lower and current density is higher. Skin contraction applications will typically function in series, while deeper tissue applications may behave as a parallel system. Paradoxical effects may be observed depending upon the electrical behavior of the system.

Modulation of RF frequency (FM) may provide additional delineation of the impedance characteristics of tissues. More specifically, an increase in the frequency may correlate to a greater thermal release in higher impedance tissues. In a "series" system, an increase in RF frequency will equate to an increase in the thermal content of target tissues that are resistors. In a parallel system, target tissues may be configured differently to augment current density in a low impedance environment. Different frequency parameters may be required.

Raising the extracellular fluid (ECF) content of soft tissue results in a reduction in tissue impedance, which increases current density and thermal delivery to target tissues that have a relatively higher impedance. Target tissues can also be physically manipulated to lower ECF content and further raise their local tissue impedance as resistors. The thermal energy released at a target tissue is expressed as joules, or the heat dissipated in an electrical system. The thermal energy released at the target tissue is directly related to the tissue impedance and is exponentially related to the current density.

An understanding of tissue impedance in reference to the different phases of the wound healing sequence is critical in predicting thermal remodeling effects upon collagen. In general, conductors such as inflammatory edema or normal saline will increase the extracellular fluid. Transfer of RF energy through tissue without thermal release is facilitated. Injection of glucose containing solutions or conditions that

reduce the ECF will act as resistors that will target tissue for thermal release and the remodeling of collagen.

The following is a tissue impedance scale:

Conductors

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Resistors

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Saline..... Edema..... Immature/..... Mature.....

Glucose..... Native

Fibroplasia

Scar Collagen

Collagen

15 If the wound healing sequence is examined, the initial stage involves the creation of inflammatory edema that raises ECF and conductance. Following a lag period of three to five days, the second phase of fibroplasia involves the multiplication and migration of fibroblasts to the wound. The deposition of scar collagen will increase tissue impedance even though (ECF) ground substance content is high.

20 The final phase of scar collagen maturation begins at two weeks and continues for several weeks. During this phase, the collagen becomes progressively more insoluble due to the loss of ground substance with a concomitant increase in intermolecular and interfiber cross linkage. Concurrent with this change is a gradual increase in tissue impedance.

25 Preexisting or native collagen is even more insoluble and will exhibit the highest tissue impedance.

The ability of energy to do work in this soft tissue system corresponds to the contraction of collagen by the disruption of crosslinks

in the triple helix of the molecule. An accurate measure of energy delivery to the tissue is required. Temperature is not a measure of heat content or energy delivery to tissue. Rather, it is a momentary snapshot of the energy level of the tissue. It is the delivery of energy over time as the heat content (joules/second) that is the most accurate measure of energy available for the contracture of collagen. Another factor that affects the heat content of tissue is the thermal dissipation that occurs through thermal conduction away from the target tissue and the thermal convection from vascular and surface structures.

Control of multiple factors is required to create the optimal RF tissue environment for the non-ablative contraction of collagen. Initially, heat is required as a precursor of the "RF effect. This may be supplied from a variety of sources, such as ultrasound. The thermal energy acts as an amplifier of the RF electrode rather than a direct agent to cleave the molecular crosslinks. This beginning thermal sequence provides the ionic agitation required for the magnetic induction by the RF electrode. The magnetocaloric effects predicts the thermal requirement for the magnetic induction of tissue and is described by $\Delta T/\Delta H = -T/CH (\partial M/\partial T)_H$, where ΔT = change in temperature, ΔH = change in magnetic field, and CH = Specific heat capacity/volume. The ionic polarization of the tissue by the RF electrode produces an alternating magnetic moment that cleaves the collagen crosslinks with an "in phase" alternating ionic motion. In other words, the magnetocaloric effect increases the induced magnetic moment within the tissue. Additional thermal energy beyond this effect will only damage tissue and should be avoided.

FM (frequency modulation) for each tissue system is crucial to achieving the most efficient reverse gradient for collagen contraction.

The appropriate frequency that is in phase with the most efficient ionic motion is provided as "work" to the system where P (watts or joules/second) = I^2R . Consequently, the tissue environment should be configured to increase current density by decreasing tissue impedance.

5 Excessive heat production from "out of phase" frictional agitation is avoided while direct ionic cleavage of collagen crosslinks is facilitated. The net result is the contraction of collagen with lower power requirements which reduces thermal damage to the tissue.

There are several methods available to alter the tissue impedance of the skin surface and soft tissue to serve either as a conduit or as a target resistor. For example, current density can be increased with the injection of a conductor (decrease TI) such as normal saline, which allows the subcutaneous plane to act as a conduit to the target tissue. Conducting fluid that increases current density to the target tissue will increase thermal release in a logarithmic fashion. In addition to lowering tissue impedance and increasing current density, saline injection into target tissues enlarges the effective surface area of the RF electrode. A more uniform inductive effect is provided by the saline tissue interface. Increasing the TI of adjacent structures by stretching skin over rollers (decreasing ECF) will have a similar effect by funneling the current to the conduit tissue. Injection of a resistor fluid, such as glucose, into a target tissue will increase the TI and thermal release in a linear fashion. Current density of conduit tissues and thermal release at target tissues is greatly enhanced by combining the injection of conducting (saline) and resisting (glucose) fluids. In other words, soft tissue injection functions as a tissue impedance "lens" that focuses thermal energy in target tissues while reducing collateral damage to adjacent structures. This approach is mainly used for deeper soft tissue applications. In general, the

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manipulation of the impedance characteristics of target tissues with either conductors or resistors will create the optimal RF environment that has the appropriate amount of heat and current density for the magnetic induction of that tissue.

5 For skin applications, an understanding of dermal impedance is required. Reduction in the thermal load at the skin entry port subjacent to the RF electrode may be accomplished by reducing the tissue impedance of the skin with hydration, i.e. a hydrogel applied under the electrode strip is used to increase ECF and conductivity of the skin entry point. A more
10 selective (time-dependent) hydration of the epidermis and papillary dermis under the electrode will conduct current through the superficial skin and target the deeper dermis as a resistor. This pre-determined period of hydration is selected for the specific dermal level of the target tissue. The target tissue interface is positioned between the overlying
15 hydrated conducting skin and the subjacent non-hydrated dermis that acts as a resistor. A RTG for dermal and subdermal contraction of skin is achieved when the current is released as thermal energy in the deeper dermal tissue. More specifically, hydration of the skin is achieved by initially applying an anesthetic gel that has an aqueous penetrant
20 formulation. The treatment area is then submerged in a bath for a variable period of time, as dictated by the dermal target level. This specific methodology would have cutaneous applications for scar collagen deposition and contraction to correct wrinkling and aging of the skin. Wrinkling of the skin is treated by targeting a more superficial dermal
25 level and is achieved by reducing the duration and depth of skin hydration. Deeper dermal effects for skin contraction would be achieved by longer periods of skin hydration. In addition, the deeper dermal and subdermal target tissues can be discriminated further from the conducting

superficial skin with the injection of a fluid resistor such as glucose. Heating of the glucose prior to injection in the target tissue may additionally serve to lower the RF power requirement for contraction of collagen. The "tumescent" technique used for liposuction could be used
5 as a familiar technique of injection.

Another approach to alter TI is to invoke the inflammatory stage of the wound healing sequence. Similar to the induction of scar collagen deposition, the wound healing sequence can be initiated to alter the TI and current density of soft tissue. The initial inflammatory stage of the wound
10 healing sequence involves creation of edema fluid within the extracellular spaces. The ECF will be increased as edema fluid and will allow tissue to act as a conductor/conduit. This fluid is a conductor whose osmolarity is similar to normal saline and is formed by the extravasation of serum from the capillary bed or post capillary venules. Changes in endothelial
15 permeability as mediated by histamine and bradykinin will appear morphologically as erythema of the skin. Various modalities are available to incite this inflammatory phase. The topical application of mechanical, thermal, chemical or pharmacological agents to induce cutaneous inflammatory edema will allow current to be conducted through the skin
20 without thermal damage. Retin A, alpha hydroxy acids, and dilute TCA may be applied to lower surface impedance and thermal damage at the skin entry point.

In addition, the stability of the triple helix can be chemically altered prior to thermal denaturization. The collagen shrinkage
25 temperature (Ts) is an indication of molecular stability as is determined by the amount of crosslinkage. Ground substance such as chondroitin sulfuric acid (CSA) increases molecular stability by promoting salt-like crosslinks between collagen fibers. Reagents such as hyaluronidase

(Wydase) that enzymatically remove CSA will reduce fiber stability and the shrinkage temperature (T_s). Typically, a reduction of 10 °C in the T_s is obtained by the injection of this reagent. As a result, power requirements and thermal damage to conducting and target tissues would be reduced. Wydase may be combined with a resistor fluid such as glucose to augment thermal release while lowering the temperature required for contraction. Typically, the solution would be combined with a dilute local anesthetic and injected into target tissues with the "tumescent" technique.

Pharmacological methods to alter the solubility of collagen may also be an effective way to alter the relative conductance and resistance of soft tissue. Anti-inflammatory medications such as steroids will reduce conductance and edema fluid of target tissues. Other agents such as vitamin E will also reduce conductance by promoting the scar maturation process. During this process, the decrease in collagen solubility is due to loss of ground substance and an increase in molecular cross linkage. Reversing the maturation process involves increasing the solubility of collagen with various lathrogenic agents (such as beta aminopropionitrile, d-penicillamine and colchicine). Cross linkage is retarded and the tissue will exhibit a higher conductance due to the increase in ground substance. These various pharmacologic agents can be administered either topically, systemically or by direct injection.

In contrast to the application of energy, manipulation of energy losses in the system provides another means to achieve the contraction of collagen without surface ablation. Thermal conduction losses occur through the passive dissipation of heat through tissue and is limited by local tissue parameters. In contrast, convection transfer of heat occurs through the physical movement of heated matter away from the target

tissue and is a process that can be actively manipulated. Flash cycles of surface cooling interspersed with heating will allow greater heat dissipation at the surface than the underlying dermal tissue. Sequential cycles of surface cooling and tissue heating provide a RTG as the heat
5 dissipated from surface convection occurs faster than subdermal conductive losses. A progressive increase in the subdermal heat content occurs while maintaining a constant surface temperature.

Promoting energy losses with surface convection cooling is a necessary adjunct to contracting collagen without collateral thermal
10 damage from excessive ionic friction and agitation. A surface convection cooling pad should cool tissues but provide enough thermal energy required by the magnetocaloric effect for the magnetic induction and cleavage of molecular collagen crosslinks.

Other approaches to reduce the thermal load to the skin surface can
15 be employed. Dispersion of current density over a larger surface area will reduce the thermal load to the skin surface. Multiple port focusing with RF and ultrasound in a tandem fashion will have a similar effect of dispersing energy. Between the electrode strips, a non-conductive medium can be used to directly preheat the dermal and subdermal target
20 tissues. A combination of these modalities can be employed to avoid thermal damage to the skin surface.

Additional device modalities are available to physically manipulate tissue and decrease ECF, i.e. the manipulated tissue behaves like a resistor. These devices may be applied in tandem or as part of the RF
25 electrode. They include rollers, suction cups or a combination of both. Simple mechanical trauma such as rolling the skin will initially increase the TI, but may subsequently augment conductance of the skin with the formation of inflammatory edema at the current entry area of skin under

the electrode. As a more efficient conductor of current, the skin surface will avoid thermal damage and allow more efficient delivery of energy to target tissues. Target tissues will also respond in a similar fashion with the formation of inflammatory extracellular fluid. Although an initial
5 drop in TI will be observed, the solubility and conductance will decrease with the deposition of scar collagen within 72 hours after initial injury. Subsequent treatment may be timed to take advantage of the increasing resistance of the target tissue to provide a greater release of thermal energy. Additional scar maturation with increased cross linkage may
10 make the collagen more susceptible to contraction from both a TI and a chemical bonding perspective, even though the shrinkage temperature (Ts) is raised. In general, collagen maturation with additional cross-linkage will increase the potential for contraction. Mature or native collagen should exhibit a greater thermal release (TI increase) and
15 molecular contraction than more soluble and immature scar collagen.

A cross indexing of these approaches should reveal an appropriate combination of methods for each clinical application. Monopolar and bipolar patterns of current density in combination with these methods that alter tissue conductance will allow greater latitude in shaping the specific
20 pattern of RF energy delivery.

The present invention involves application of a RTG to heat the underlying dermal collagen, while protecting the superficial epidermal skin. The device used to achieve this effect is similar to a heating pad. It employs radio frequency (RF) energy that is precisely focused on the
25 underlying dermal collagen of treatment areas.

In addition, this energy source can be employed in tandem with other energy sources. Ultrasound can be used as a non-inductive source can provide the initial energy of ionic agitation required for the magnetic

RF induction of collagen containing tissue. By changing the local TI with physical and pharmacological manipulation of the skin and target tissues, a more accurate delivery of thermal energy is achieved. Partial denaturization of collagen is achieved with each application and the use of sequential treatments will allow for more precision of the end result.

Depending upon the topography of a treatment area, the heating pad is designed to provide the appropriate vectors of contraction. Areas of application are not confined by requirements to hide surgical incisions or to transition chemical peels or laser resurfacing into aesthetic boundaries. And since scarring and pigmentary irregularities are avoided, skin tightening can now occur in areas previously considered "off-limits" to standard methods of correction.

The medical devices and procedures that are designed specifically for skin contraction will have the following components: initially, the skin is hydrated to a specific dermal level before the RF heating pad is applied. This allows conductance of RF energy through the skin without thermal release. The subjacent dermis which has not been hydrated will respond as a resistor with the release of thermal energy to contract or induce collagen. In addition, ultrasound transducers are incorporated with mechanical rollers that are applied as a separate device over the RF heating pad. The rollers manipulate tissue impedance and the ultrasound transducers are aligned as parallel opposing ports that are focused with an overlapping energy pattern at the target dermal level. By simultaneously heating the target tissue with ultrasound, power requirements are reduced for the RF heating pad.

The initial evaluation is begun with a digitized image of the patient. Each potential treatment area is captured for analysis. A cursor is used to determine the appropriate boundary of each treatment area for either a

minimally invasive or non-invasive approach. For non-invasive skin contraction or soft tissue remodeling, a vector analysis is performed to orient the parallel electrode array on the patient's skin. For the minimally invasive contraction of skin and soft tissue, an intraoperative infrared image is captured and referenced to the preoperative digital evaluation. During the procedure, the peak infrared emission pattern for each area is captured and digitally incorporated into an entire mosaic of the treatment area. This peak emission mosaic is compared to the preoperative digital evaluation for the position, boundary and appropriate vectors of contraction in addition to the recommended infrared emission levels. With this method of preoperative and intraoperative analysis, an accurate depiction of the post operative result can be provided to the patient during the initial preoperative evaluation.

Taking into consideration many of the methodologies that have been discussed to achieve a RTG contraction of collagen, the following provides a sample application sequence. A treatment sequence for clients desiring skin contraction involves a variety of modalities.

For one week prior to treatment, a topical agent such as Retin A or alpha hydroxy acid is applied to the skin to produce an inflammatory edema. Conductance of RF energy through the superficial skin will be facilitated. The client begins her treatment session with the application of an aqueous penetrant gel which contains a concentrated local anesthetic. The gel is massaged into the specifically marked treatment areas for 30 minutes. These areas are preferentially hydrated by having the client bathe for approximately one hour with water temperature approximately 100° F. Actual bathing time will vary depending upon the treatment level within the skin. Additional preparation of the treatment area may require injection of impedance altering fluids such as saline (conductor) or

glucose (resistor). This solution may be combined with Wydase and xylocaine to lower power requirements and provide anesthesia. The solution is injected with the "tumescent" technique. This technique, typically used for deeper soft tissue applications, may be employed for skin contraction. The next stage of the treatment sequence involves the application of the RF heating pad that has been specifically configured from the treatment area. Incorporated into the RF heating pad is a cooling channel that will cycle dermal heating and surface convection cooling. A second device that employs mechanical rollers and ultrasound transducers to focus additional thermal energy in the skin may also be used. Multiple treatments of this non-invasive program provides for greater precision of the end result while avoiding blistering of the skin. In addition, periodic maintenance treatments will be required to counter the continuation of the aging process.

Minimally invasive techniques are possible that involve the percutaneous insertion of a medical device through the skin that can achieve a RTG for the contraction of skin. The device can be used in tandem with an endoscope to provide hemostasis and aid the dissection of the subcutaneous plane. The device consists of a multiple purpose canula that is used for subcutaneous dissection and liposuction in addition to collagen contraction. In one embodiment, a spatula shaped canula has a light source on the dorsal surface which trans illuminates the skin and creates a focused light pattern on the skin to determine depth and uniformity of the subcutaneous plane of dissection. A liposuction portal is placed on the ventral aspect of the device and allows aesthetic modification of the subcutaneous fat. A separate energy source is also mounted on the dorsal aspect of the canula and is used to "paint" the subdermal and dermal tissues for the contraction of collagen. This device

may either be a separate canula with the transilluminator or combined as a single combined device with the subcutaneous dissection/suction canula. Typically an RF electrode is utilized as the primary energy source. Other energy sources may include an ultrasound transducer or a coherent CO₂ light source with a diffuser.

For example, a facelift procedure would typically involve the initial injection of a tumescent solution that contains a dilute xylocaine/epinephrine mixture with added Wydase. Anesthesia and vasoconstriction with lowering of the collagen shrinkage temperature (Ts) is provided with this solution. Through small 1 cm preauricular and submental incisions, the subcutaneous dissection/ liposuction canula is inserted. Through a separate 1 cm incision, an endoscope may be inserted for direct visualization and hemostasis. After development of a uniform superficial subcutaneous plane of dissection, liposculpture of the underlying subcutaneous tissue is achieved. With a separate or combined canula, skin contraction is achieved in a uniform fashion by sweeping the energy source in the superficial subdermal plane of dissection. Accurate surface and depth orientation is provided by the transillumination pattern of the skin.

Another example of a minimally invasive procedure is the correction of the post partum ptosis of the breast. Typically, large anchor shaped incisions are employed to achieve a mastopexy or breast uplift. In contrast, uplifting and tightening of the breast envelope can be achieved through small periareolar incisions with the minimally invasive methodology of The present invention. Achievement of a three-dimensional enhancement rather than a two-dimensional uplifting is provided by preoperatively determining the appropriate vectors of contraction with digital capture software, i.e. a radial pattern of sweeping

will result in a longitudinal shortening of the breast envelope, whereas a circular sweeping pattern around the circumference of the breast will increase projection by tightening the base perimeter dimension. With this approach, a variety of esthetic procedures is also possible for the abdomen, thighs and arms.

The present invention provides the esthetic surgeon with the opportunity to achieve a more immediate result in a minimally invasive fashion. The larger incisions of typical esthetic procedures is eliminated. Contour irregularities and skin looseness that is typical of suction lipectomy procedures is avoided.

The same concepts of altering tissue impedance (TI) for collagen contraction can be applied for tissue ablation. Although higher power levels are required, effective radiation doses for tumor ablation can be reduced by potentiating energy release at target tissues through the manipulation of tissue impedance. As a direct benefit, the collateral damage to normal adjacent structures would be minimized.

Power requirements for cancer management can be reduced further by altering intracellular metabolism rather than ablating tumor cells. If remission or homeostasis is defined as a state in which net tumor growth has ceased, then the creation of a state can be achieved by increasing cell death (ablation) or decreasing cell growth by suppression of mitosis with intracellular thermal induction. Most oncologic treatment modalities focus upon various ablation strategies that place little emphasis on reducing mitotic activity. Suppression of cancer cell mitosis with intracellular thermal induction has significant potential in reestablishing homeostasis at lower power requirements. The patient care algorithm would consist of a continuing sequence of treatments to maintain the balance between cell death and cell growth while eliminating damage to

adjacent tissue. The thermal induction of homeostasis will also provide a continuing opportunity for a competent immune response by the patient. A balance between ablation and thermal induction of homeostasis is also promoted by selectively altering the tissue impedance of target and
5 conducting tissues. Power or dose requirements for ablation can be further reduced by modifying the cellular kinetics of the tumor. Thermal induction will place cells in phase during the mitotic cycle, rendering the tumor more susceptible to ablation. Cycles of treatment with thermal induction will stagger phases of cell multiplication to predictable periods
10 that can be timed with the patient's oncologic treatment (i.e. chemotherapy and/or radiation therapy). By increasing the specificity of thermal ablation, sequential management of metastatic disease may be possible.

Thermal ablation of normal tissue can be used for aesthetic liposculpture. By altering TI and conductance with these methods,
15 ablation of subcutaneous fat can be achieved with a greater degree of precision. The current use of "tumescent" injection of an impedance altering solution integrates easily with the present invention.

Non-ablative thermal modification of intracellular metabolism is another potential application with this technology. If a low grade injury
20 pattern is sustained during exercise, thermal injury should incite the same sequence of extracellular and intracellular inflammation that leads to hypertrophy of a muscle cell. This method can be applied for disuse atrophy of muscle in patients who are paraplegic or who are in catabolic stress for any reason. Disuse atrophy sustained in zero gravity
25 environments may be avoided with intracellular thermal induction of muscle.

It may also be possible to modulate the synthesis of collagen by the fibroblast with a combination of both intracellular and extracellular

thermal induction. The thermal inductive effects should be different for intracellular suppression of collagen synthesis than scar collagen formation as provided by the wound healing sequence. A direct application of intracellular thermal suppression of collagen synthesis and fibroblast mitosis is the reduction of hypertrophic scarring in surgical incisions.

Bony callus formation and formation by the osteoblast may also be modulated by the selective balance between intracellular and extracellular thermal inductive effects.

Alternately, the healing by regeneration instead of scarring may be influenced by the selective thermal induction of intracellular and extracellular processes. Regeneration of soft tissue structures may occur more readily in a conducting milieu than in an impedance environment which would promote the deposition of scar collagen. Peripheral nerve regeneration should be aided by selectively suppressing scar formation at the proximal stump of a transacted nerve, and the demyelination of nerve fibers could be prevented with this modality. Determining the impedance/conductance conditions and electromagnetic field pattern of fetal development should provide necessary information to promote healing by regeneration. The intracellular degeneration and cell membrane dissolution of the cerebral cortex may be prevented by maintaining the appropriate magnetic field around these structures.

Definitions of Standard Gradients

A Standard Thermal Gradient is the application of electromagnetic energy. The soft tissue without modification of surface angle incidents or tissue parameters that change energy transmission and release in that tissue.

5 **A Standard Gradient of Molecular Collagen Contraction and Cellular Contraction of Collagen Containing Tissue** is the contraction of that tissue without modification of surface energy angle incidents or tissue parameters that change energy transmission and release within that tissue.

10 **A Standard Gradient of Energy Delivery** is the delivery of energy into tissue without modification of surface incidents or tissue parameters that change energy transmission and release within that tissue.

15 **A Standard Gradient of Tissue Interaction** is the interaction of tissue with energy without modification of surface angle incidents or tissue parameters that would change the pattern of tissue interaction with energy.

Definitions of Reverse Gradients

20 **A Reverse Thermal Gradient** is defined by its relationship to a Standard Thermal Gradient.

25 **A Reverse Thermal Gradient** is cooler on the surface or in adjacent tissues when compared to a Standard Thermal Gradient that has a target tissue with the same heat content.

A Reverse Thermal Gradient can also be expressed as:

30 1. A reduced Standard Thermal Gradient between the surface and underlying tissue, or between adjacent and target tissues.

2. An Equalized Thermal Gradient between the surface and underlying tissue, or between adjacent and target tissues.
 3. A Thermal Gradient in which ablation does not occur on the surface or in adjacent tissue (next to a target).
 4. A Thermal Gradient in which ablation is reduced on the surface or adjacent tissue in comparison to a Standard Thermal Gradient.
- 10 **A Reverse Gradient of Molecular Collagen Contraction and Cellular Contraction of Collagen Containing Tissues** is defined by its relationship to a Standard Gradient Contraction of Collagen Containing Tissues.
- 15 **A Reverse Gradient of Collagen Contraction** results in the preferential contraction of a target tissue that is greater in comparison to a Standard Gradient of Collagen Contraction of target and surface/adjacent tissues.
- A Reverse Gradient of Collagen Contraction** can also be expressed as:
- 20 1. A Reduced Standard Gradient of Collagen Contraction between surface and underlying tissue or between adjacent and target tissues.
 - 25 2. As an Equalized Gradient of Collagen Contraction between the surface and underlying tissue or between adjacent and target tissues.
 - 30 3. A Gradient of Collagen Contraction in which ablation does not occur in surface or adjacent tissues.

4. A Gradient of Collagen Contraction in which ablation is reduced on the surface or adjacent tissues in comparison to a Standard Gradient of Collagen Contraction.

5 **A Reverse, Gradient of Energy Delivery** is defined by its relationship to a Standard Gradient of energy delivery.

A Reverse Gradient of Energy Delivery is the preferential delivery of energy to a target tissue that is greater in comparison to a Standard of Gradient of energy delivery regardless of the energy content of surface and adjacent tissues.

A Reverse Gradient of Energy Delivery can also be expressed as:

- 15 1. A Reduced Standard Gradient of Energy delivery between surface and underlying tissue or between adjacent or target tissues.
2. An Equalized Gradient of Energy delivery between the surface and underlying tissue or between adjacent and target tissues.
- 20 3. A Gradient of Energy delivery in which ablation does not occur on surface or in adjacent tissues.
- 25 4. A Gradient of Energy delivery in which ablation is reduced on surface or adjacent tissues in comparison to a Standard Gradient of energy delivery.

Reverse Gradient of Tissue Interaction is defined by its relationship to a Standard Gradient of tissue interaction.

30

A Reverse Gradient of Tissue Interaction is the achievement of a desired soft tissue effect on a target tissue with a reduced soft tissue effect to surface or adjacent structures in comparison to a Standard Gradient of interaction.

5 **A Reverse Gradient of Tissue Interaction** can also be expressed as:

1. A Reduced Standard Gradient of tissue interaction between surface and underlying target tissue or between adjacent and target tissues.
- 10 2. An Equalized Gradient of tissue interaction between the surface and underlying target tissue or between adjacent and target tissues.
- 15 3. A Gradient of tissue interaction in which ablation does not occur on surface or in adjacent tissues next to a target tissue.
4. A Gradient of tissue interaction in which ablation is reduced on surface or adjacent tissues next to a target tissue in comparison to
- 20 a Standard Gradient of tissue interaction.

Claims of Electromagnetic Energy and Aesthetic Enhancement

- 25
1. The Use of Electromagnetic Energy to Achieve a Reverse Gradient of Molecular Contraction of Collagen and a Reverse Gradient of Cellular Contraction in Collagen Containing Tissue without Ablation.

30

2. The Use of Electromagnetic Energy to Achieve a Reverse Gradient of Molecular Contraction of Collagen and a Reverse Gradient of Cellular Contraction in Collagen Containing Tissue with reduced Ablation in comparison to a Standard Thermal Gradient.
5
3. The Use of Electromagnetic energy in Soft Tissue to Achieve a Reverse Gradient of Energy Delivery without ablation.
- 10 4. The Use of Electromagnetic Energy in Soft Tissue to Achieve a Reverse Gradient of Energy Delivery with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 15 5. The Use of Electromagnetic Energy in Soft Tissue to Achieve a Reverse Gradient of Energy Delivery with Ablation of Target Tissue but without Ablation of Surface or Adjacent Tissues.
- 20 6. The Use of Electromagnetic Energy in Soft Tissue to Achieve a Reverse Gradient of Energy Delivery with Ablation of Target Tissue but with reduced Ablation of Surface or Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 25 7. The Use of Electromagnetic Energy to Reconfigure the Surface and Contour of Soft Tissue with a Reverse Gradient of Energy Delivery.
- 30 8. The Use of Electromagnetic Energy to Reconfigure the Surface Contour of Soft Tissue with a Reverse Cellular and Extracellular Gradient of Energy Delivery.

- 5
9. The Use of Electromagnetic Energy to Reconfigure the Surface and Contour of Soft Tissue with a Reverse Cellular and Extracellular Gradient Contraction of Collagen Containing Tissues.
- 10
10. The Use of Reverse Gradient of Energy Delivery to Alter the Intracellular Metabolism of Soft Tissue (use different cell types as dependent claims; the adipocyte, myocyte, fibroblast, fibrocyte, epidermal cell, melanocyte, osteoblast, osteocyte, neuron, skin adnexal cells - hair follicle, sebaceous gland, sweat gland).
- 15
11. The Use of a Reverse Gradient of Energy Delivery to Achieve Molecular Contraction of Collagen and Cellular Contraction of Collagen Containing Tissues.
12. The Use of a Reverse Gradient of Energy Delivery to Alter the Extracellular Metabolism of Soft Tissue.

20 **Dependent Claims of Electromagnetic Energy and Aesthetic Enhancement**

1. The Use of Electromagnetic Energy to Alter Soft Tissue Volume with a Reverse Gradient of Energy Delivery:
- 25 a. Without Ablation.
- b. With Reduced Ablation in Comparison to a Standard Gradient.
- 30 c. With Ablation.

2. The Use of Electromagnetic Energy to Alter Soft Tissue Consistency with a Reverse Gradient of Energy Delivery:
- 5 a. Without Ablation.
- b. With Reduced Ablation in Comparison to a Standard Gradient.
- 10 c. With Ablation.
3. The Use of Electromagnetic Energy to Alter the Overall Function of a Soft Tissue Structure with a Reverse Gradient of Energy Delivery:
- 15 A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient.
- C. With Ablation.
- 20 4. The Use of a Reverse Gradient of Energy Delivery to Reconfigure the Surface and Contour of Soft Tissue by Altering the Intra-cellular Processes (metabolism), of Component Cells, i.e., the adipocyte, myocyte, fibroblast, fibrocyte, epidermal cell, melanocyte, osteoblast, osteocyte, neuron, skin adnexal cells - hair follicle, sebaceous gland,
- 25 sweat gland.
- A. Without Ablation.
- 30 B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Cells in a Target Area.

5. The Use of a Reverse Gradient of Energy Delivery to Change the Consistency of Soft Tissue by Altering the Intra-cellular Processes of Component Cells, i.e., the adipocyte, myocyte, fibroblast, fibrocyte, epidermal cell, melanocyte, osteoblast, osteocyte, neuron, skin adnexal cells - hair follicle, sebaceous gland, sweat gland.
- 5
- A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Cells in a Target Area.
- 10
6. The Use of a Reverse Gradient of Energy Delivery to Change the Volume of Soft Tissue by Altering the Intra-cellular Processes of Component Cells, i.e., the adipocyte, myocyte, fibroblast, fibrocyte, epidermal cell, melanocyte, osteoblast, osteocyte, neuron, skin adnexal cells - hair follicle, sebaceous gland, sweat gland.
- 15
- A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Cells in a Target Area.
- 20
7. The Use of a Reverse Gradient of Energy Delivery to Change the Overall Function of a Soft Tissue Structure by Altering the Intra-cellular Processes of Component Cells, i.e., the adipocyte, myocyte, fibroblast, fibrocyte, epidermal cell, melanocyte, osteoblast, osteocyte, neuron, skin adnexal cells - hair follicle, sebaceous gland, sweat gland.
- 25
- A. Without Ablation.
- 30

- B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Cells in a Target Area.
- 5 8. The Use of a Reverse Gradient of Energy Delivery to Change the Growth of a Soft Tissue Structure by Altering the Intra-cellular Processes of Component Cells, i.e., the adipocyte, myocyte, fibroblast, fibrocyte, epidermal cell, melanocyte, osteoblast, osteocyte, neuron, skin adnexal cells - hair follicle, sebaceous gland, sweat gland.
- 10 A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Cells in a Target Area.
- 15 9. The Use of a Reverse Gradient of Energy Delivery to Change the Extracellular Metabolism of a Soft Tissue Structure.
- A. Without Ablation.
- 20 B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Extracellular Tissue in a Target Area.
- 25 10. The Use of a Reverse Gradient of Energy Delivery to Reconfigure the Surface and Contour of Soft Tissue by Altering the Extracellular Metabolism of that Tissue.
- A. Without Ablation.
- 30 B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Extracellular Tissue in a Target Area.

11. The Use of a Reverse Gradient of Energy Delivery to Change the Volume of Soft Tissue by Altering the Extracellular Metabolism of that Tissue.
- 5 A. Without Ablation.
- B. With Reduced Ablation in Comparison to - a Standard Gradient of Remaining Extracellular issue in a Target Area.
- 10 12. The Use of a Reverse Gradient of Energy Delivery to Change the Consistency of Soft Tissue by Altering the Extracellular Metabolism of that Tissue.
- 15 A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Extracellular Tissue in a Target Area.
- 20 13. The Use of a Reverse Gradient of Energy Delivery to Change the Overall Function of Soft Tissue by Altering the Extracellular Metabolism of that Tissue.
- 25 A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of Remaining Extracellular Tissue in a Target Area.
- 30 14. The Use of a Reverse Gradient of Energy Delivery to Change the Growth of Soft Tissue by Altering the Extracellular Metabolism of that Tissue.

- 5
- A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of
Remaining Extracellular Tissue in a Target Area.
15. The Use of a Reverse Gradient of Energy Delivery to Change the
Intracellular Metabolism of a Soft Tissue Structure.
- 10
- A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of
Remaining Cells in a Target Area.
- 15
16. The Use of a Reverse Gradient of Energy Delivery to Change the
Extracellular Metabolism of a Soft Tissue Structure.
- A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of
20 Remaining Extracellular Tissue in a Target Area.
17. The Use of Electromagnetic Energy with a Reverse Gradient of Energy
Delivery to Achieve Molecular Contraction of Collagen and Cellular
Contraction of Collagen Containing Tissues Remaining in an Ablation
25 Target.
18. The Use of Electromagnetic Energy to Alter Soft Tissue Volume with a
Reverse Cellular and Extracellular Gradient Contraction of Collagen
Containing Tissues.
- 30
- A. Without Ablation.

- 5 B. With Reduced Ablation in Comparison to a Standard Gradient of
 Remaining Soft Tissue.
19. The Use of Electromagnetic Energy to Alter the Soft Tissue Consistency
5 with a Reversed Cellular and Extracellular Gradient Contraction of
 Collagen Containing Tissues.
- A. Without Ablation.
- 10 B. With Reduced Ablation in Comparison to a Standard Gradient of
 Remaining Soft Tissue.
20. The Use of Electromagnetic Energy to Alter the Overall Function of a
15 Soft Tissue Structure with a Reverse Cellular and Extracellular Gradient
 Contraction of Collagen Containing Tissues.
- A. Without Ablation.
- B. With Reduced Ablation in Comparison to a Standard Gradient of
20 Remaining Soft Tissue.

Additional Claims

- 25 1. Additional Claims for Manipulation of RF Parameters (FM, Power), to
 Achieve the Most Efficient Ionic Magnetic Moment for the Cleavage of
 Collagen Bonds and the Molecular Contraction of Collagen.

Miscellaneous Claims

1. Manipulation of Electromagnetic Energy to Achieve the Most Efficient Cleavage of Collagen Bonds for Contraction with the Smallest Amount of Thermal Damage to Surface and Adjacent Tissues.
- 5 2. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve Collagen Contraction with a Minimal Amount of Thermal Damage to Soft Tissue.
- 10 3. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissues without Ablation.
- 15 4. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 20 5. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissue with Partial Ablation of Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 25 6. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
7. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve Ablation of a Target Tissue with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.

8. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Most Efficient Moment of Energy Delivery for the Contraction of Collagen Containing Tissues without Ablation.
- 5 9. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Most Efficient Moment of Energy Delivery for the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 10 10. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Most Efficient Moment of Energy Delivery for the Contraction of Collagen Containing Tissue with Partial Ablation of Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 15 11. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Most Efficient Moment of Energy Delivery for Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
- 20 12. The Manipulation of Electromagnetic Energy and Tissue Parameters to Achieve the Most Efficient Moment of Energy Delivery for Ablation of a Target Tissue with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 25 13. The Manipulation of Laser Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 30 14. The Manipulation of Laser Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissue with Partial Ablation of

Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.

- 5 15. The Manipulation of Laser Energy and Tissue Parameters to Achieve Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
- 10 16. The Manipulation of Laser Energy and Tissue Parameters to Achieve Ablation of a Target Tissue with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 15 17. The Manipulation of Ultrasound Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 20 18. The Manipulation of Ultrasound Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissue with Partial Ablation of Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 25 19. The Manipulation of Ultrasound Energy and Tissue Parameters to Achieve Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
- 30 20. The Manipulation of Ultrasound Energy and Tissue Parameters to Achieve Ablation of a Target Tissue with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
21. The Manipulation of Microwave Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.

- 5
22. The Manipulation of Microwave Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissue with Partial Ablation of Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
23. The Manipulation of Microwave Energy and Tissue Parameters to Achieve Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
- 10 24. The Manipulation of Microwave Energy and Tissue Parameters to Achieve Ablation of a Target Tissue with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 15 25. The Manipulation of Mechanical Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 20 26. The Manipulation of Mechanical Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissue with Partial Ablation of Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 25 27. The Manipulation of Mechanical Energy and Tissue Parameters to Achieve Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
- 30 28. The Manipulation of Mechanical Energy and Tissue Parameters to Achieve Ablation of a Target Tissue with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.

29. The Manipulation of Frictional Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 5 30. The Manipulation of Frictional Energy and Tissue Parameters to Achieve the Contraction of Collagen Containing Tissue with Partial Ablation of Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.
- 10 31. The Manipulation of Frictional Energy and Tissue Parameters to Achieve Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
- 15 32. The Manipulation of Frictional Energy and Tissue Parameters to Achieve Ablation of a Target Tissue with Reduced Ablation of Surface and Adjacent Tissues in comparison to a Standard Thermal Gradient.
- 20 33. The Manipulation of RF Energy and Tissue Parameters to Provide the Most Efficient Magnetic Moment of Energy Delivery for the Contraction of Collagen Containing Tissues without Ablation.
- 25 34. The Manipulation of RF Energy and Tissue Parameters to Provide the Most Efficient Magnetic Moment of Energy Delivery for the Contraction of Collagen Containing Tissues with Reduced Ablation in Comparison to a Standard Thermal Gradient.
- 30 35. The Manipulation of RF Energy and Tissue Parameters to Provide the Most Efficient Magnetic Moment of Energy Delivery for the Contraction of Collagen Containing Tissue with Partial Ablation of Target Tissue, but with Reduced Ablation of Surface and Adjacent Tissues in Comparison to a Standard Thermal Gradient.

36. The Manipulation of RF Energy and Tissue Parameters to Provide the Most Efficient Magnetic Moment of Energy Delivery for Ablation of a Target Tissue without Ablation of Surface and Adjacent Tissues.
- 5 37. The Use of Thermal Energy as a Magnetocaloric Effect for the Initial Ionic Agitation that Facilitates the RF Polarization of Soft Tissue and Provides the Most Efficient Magnetic Moment with the cast Thermal Damage of Tissue to Achieve a Change in the Surface and Contour of Soft Tissue.
- 10 38. The Use of Thermal Energy as a Magnetocaloric Effect for the Initial Ionic Agitation that Facilitates the RF Polarization of Soft Tissue and Provides the Most Efficient Magnetic Moment with the cast Thermal Damage of Tissue to Achieve Contraction of Collagen Containing
- 15 Tissues.
39. The Use of Thermal Energy to Create the Initial Ionic Agitation Required by RF for the Magnetic Induction of Soft Tissue.
- 20 40. The Use of RF Energy for the Magnetic Induction of Soft Tissue Which Created and in Phase Alternating Moment of Ionic Motion that Cleaves the Molecular Cross Links of a Collagen Molecule with Less Thermal Ablation than a Standard Thermal Gradient of Collagen Containing Tissue.
- 25 41. The Use of RF Energy for the Magnetic Induction and Polarization of Collagen Containing Tissue for the Creation of an in Phase Alternating Moment of Ionic Motion that Cleaves the Molecular Cross Links of Collagen with Less Thermal Ablation than a Standard Thermal Gradient.
- 30

Tissue Parameters

1. Tissue Impedance by Altering the ECF.
2. Tissue Impedance by Altering the ICF.
- 5 3. Hydration of skin.
4. Injecting of Conducting Fluid Such as Saline or Injection of Resisting Fluids Such as Glucose.
- 10 5. Creation of Inflammatory Edema to Increase ECF.
6. Use of the Scar Maturation Process to Increase Impedance by Decreasing ECF.
- 15 7. Mechanical Manipulation to Alter Impedance without Directly Changing the ECF.
 - A. Suction cups.
 - 20 B. Rollers.
8. Changing the T_s (Shrinkage Temperature of Collagen) by,
 - 25 A. Pharmacologic Methods (Wydase).
 - B. Low Level Thermal Energy Disruption of Collagen Bonds without Contraction as a Precursor to Magnetic Cleavage and Contraction of Collagen.
 - 30 C. Mechanical Manipulation (Massage), to Disrupt Bonds as a Precursor to Magnetic Cleavage, i.e., use of Friction to Decrease

T_s by Directly Cleaving Collagen Bonds and Increasing Ionic Agitation Prior to Magnetic Induction.

More Specifically, the Mechanical Manipulation of Soft Tissue will Alter Tissue Impedance During the Application of RF Energy, but When Applied as Massage During a Precursor Treatment the Following Tissue Parameters Will be Altered.

1. Lower T_s of Collagen by Direct Mechanical Cleavage of Collagen Bonds.
2. Increase Thermal Content of Soft Tissue with Frictional Creation of Heat Which Increases Ionic Agitation Prior to the Magnetic Induction by RF.

D. Facilitation of Surface Energy Losses Through Convection Cooling.

E. Altering the Thermal Conductance of the Epidermis (Stratum Corneum).

Although Hydration will Increase the Electrical Conductance of RF Current Through the Epidermis, a More Significant Effect is the Increase in Thermal Conductance to the Stratum Corneum.

Hydration of the Intracellular (ICF) Fluid of Nonviable and Viable Cellular Components of the Epidermis Occurs by the Uptake of Water in These Keratin Containing Cells. In the Process the Stratum Corneum is Changed into a Thermal Conductor Instead of Typically Functioning as a Thermal Insulator. More Specifically, Keratin is a Poor Thermal and Electrical Conductor. Hydrated Intracellular Keratin is a Better Thermal and Electrical Conductor that

Promotes Heat Transfer to Underlying Collagen Containing Tissues and
Reduces Intracellular Tissue Impedance.

5 As a Result, the Improved Transfer of Heat, Through the epidermis facilitates
the creation of a transcutaneous reverse thermal gradient.

The foregoing description of a preferred embodiment of the
invention has been presented for purposes of illustration and description.
It is not intended to be exhaustive or to limit the invention to the precise
forms disclosed. Obviously, many modifications and variations will be
10 apparent to practitioners skilled in this art. It is intended that the scope of
the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. A method for tightening skin, comprising:
providing an electromagnetic energy delivery device with an energy delivery surface;
positioning at least a portion of the energy delivery surface on a skin surface;
delivering electromagnetic energy from the energy delivery surface through the skin surface, through the skin and to an underlying collagen containing tissue;
modifying an impedance of at least a portion of the skin or the underlying collagen containing tissue;
contracting at least a portion of the collagen tissue; and
tightening the surface of the skin.
2. The method of claim 1, wherein the collagen containing tissue is heated to a temperature not exceeding 80 degrees C during a treatment of the collagen containing tissue.
3. The method of claim 1, wherein the collagen containing tissue is heated to a temperature not exceeding 75 degrees C during a treatment of the collagen containing tissue.
4. The method of claim 1, wherein the collagen containing tissue is heated to a temperature not exceeding 70 degrees C during a treatment of the collagen containing tissue.
5. A method for tightening skin, comprising:
providing an electromagnetic energy delivery device;

positioning at least a portion of the electromagnetic energy delivery device on a surface of the skin; and

controlling a delivery of a sufficient amount of electromagnetic energy through an epidermis of the surface of the skin and modify an impedance of at least a portion of an underlying collagen containing tissue or the skin without substantially creating cell necrosis in the epidermis, wherein at least a portion of the surface of the skin is tightened.

6. A method for tightening skin, comprising:

providing an electromagnetic energy delivery device;

positioning at least a portion of the electromagnetic energy delivery device on a surface of the skin; and

controlling a delivery of a sufficient amount of electromagnetic energy through an epidermis of the surface of the skin and reconfigure at least a portion of an underlying collagen containing tissue without substantially creating cell necrosis in the collagen containing tissue; and

modifying a thermal conductivity of the skin, wherein at least a portion of the surface of the skin is tightened.

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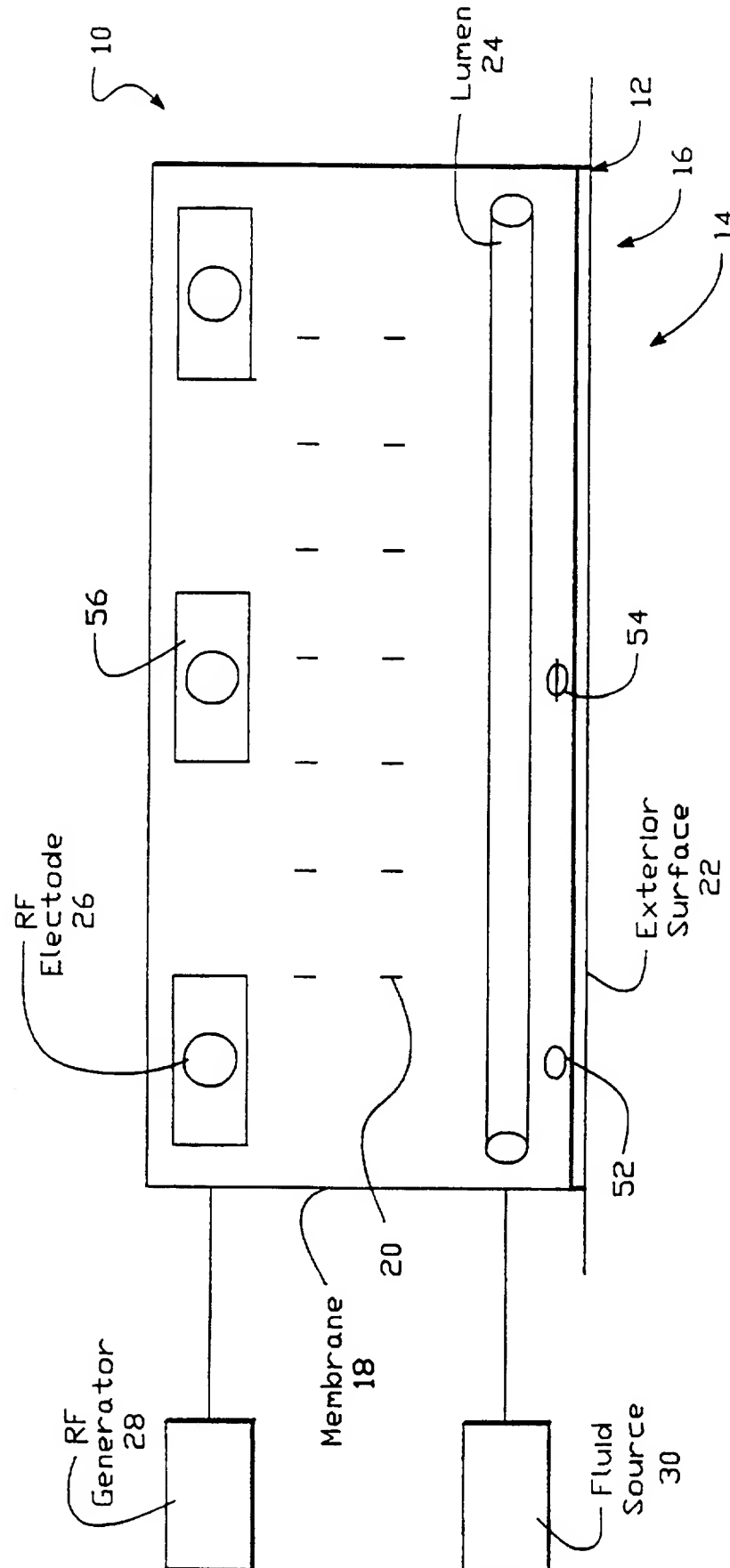


FIG. 1

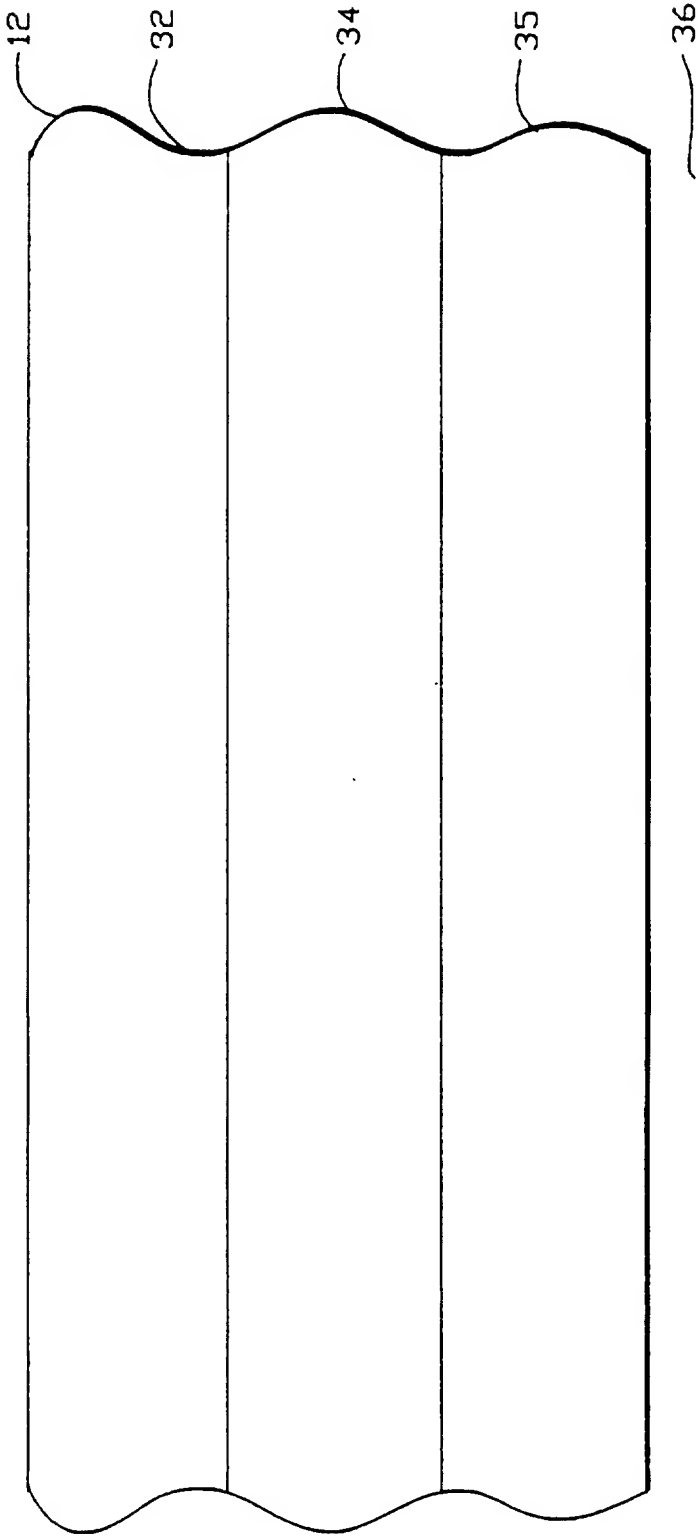


FIG.2

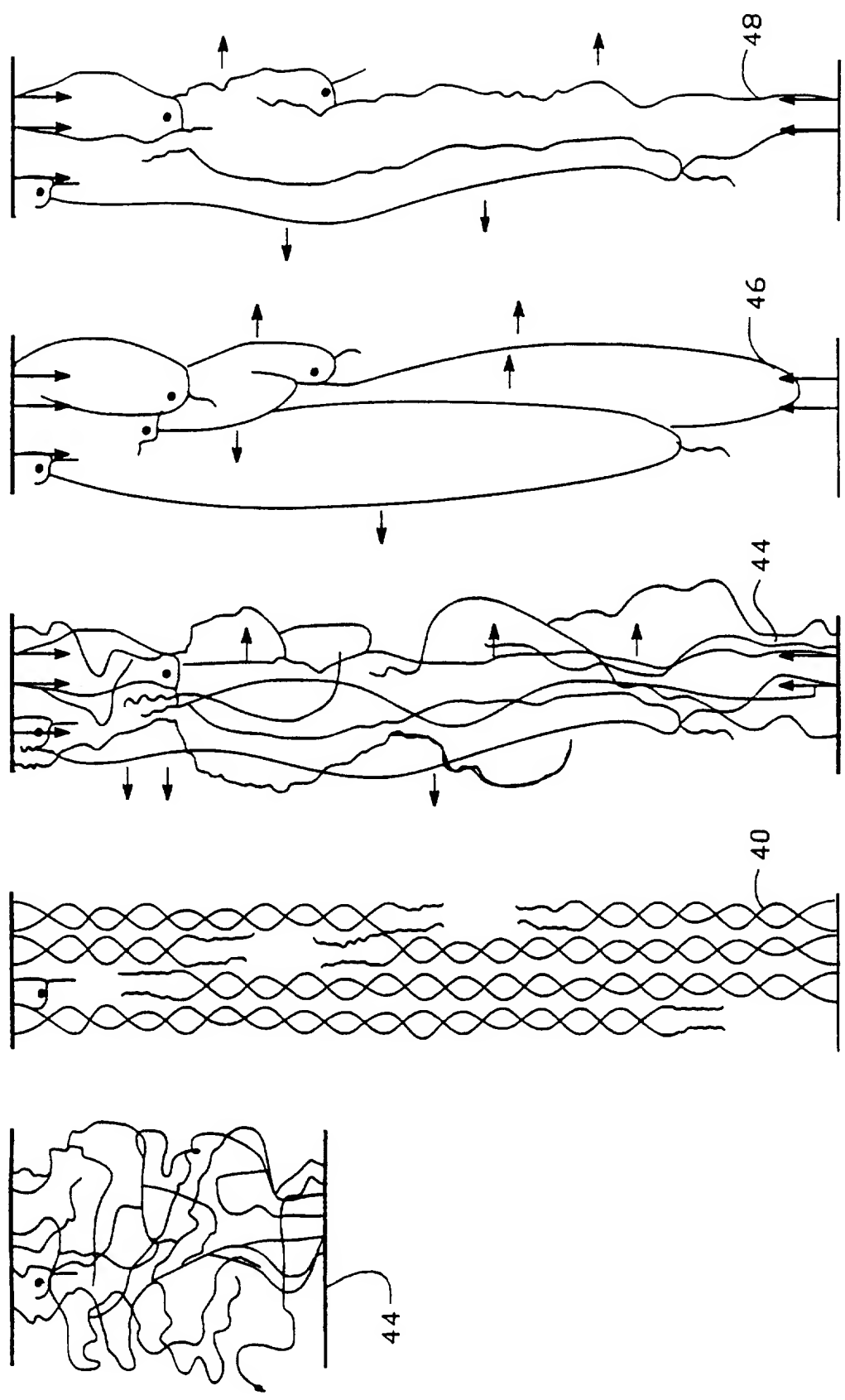


FIG.3

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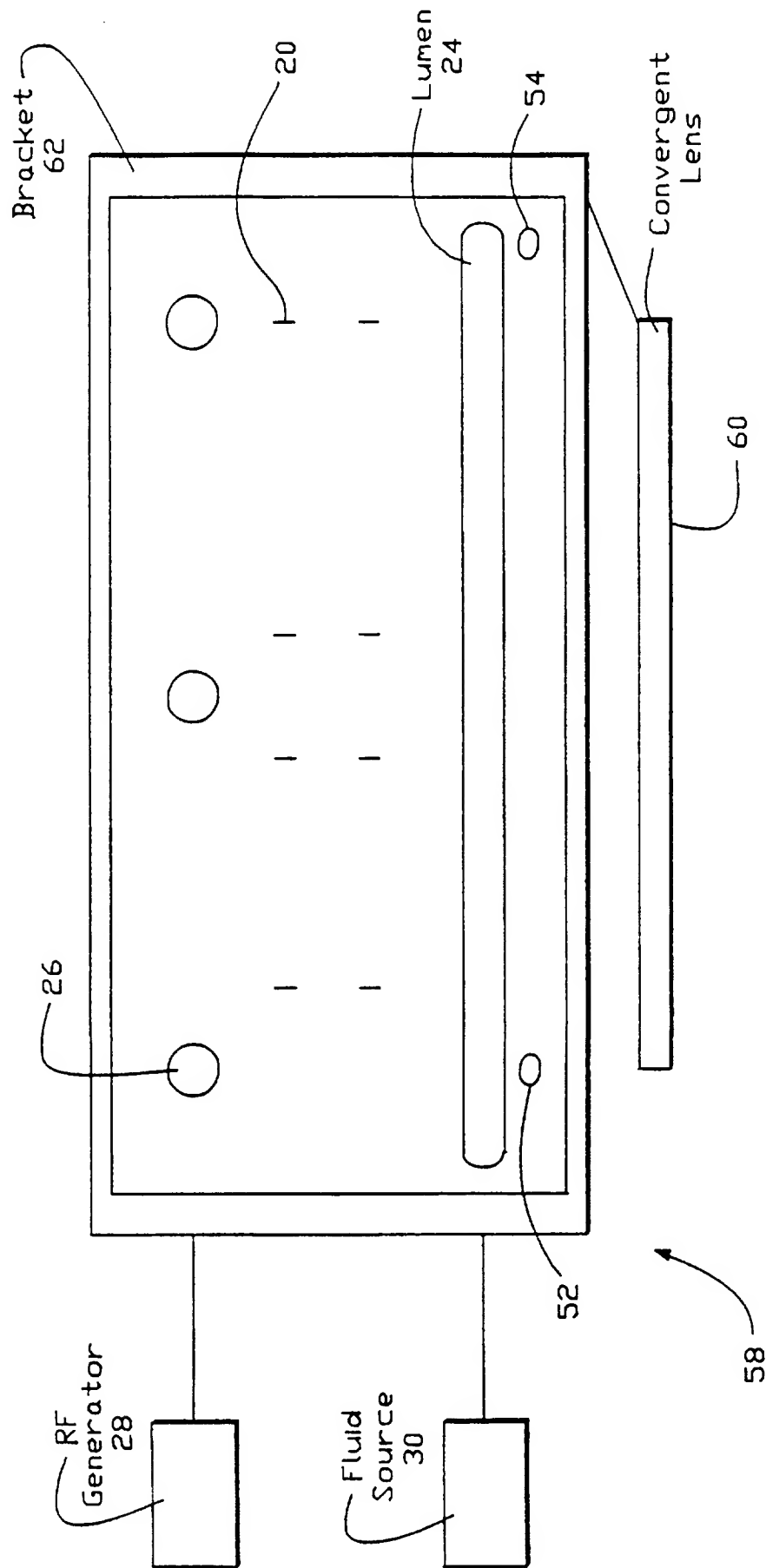


FIG. 4

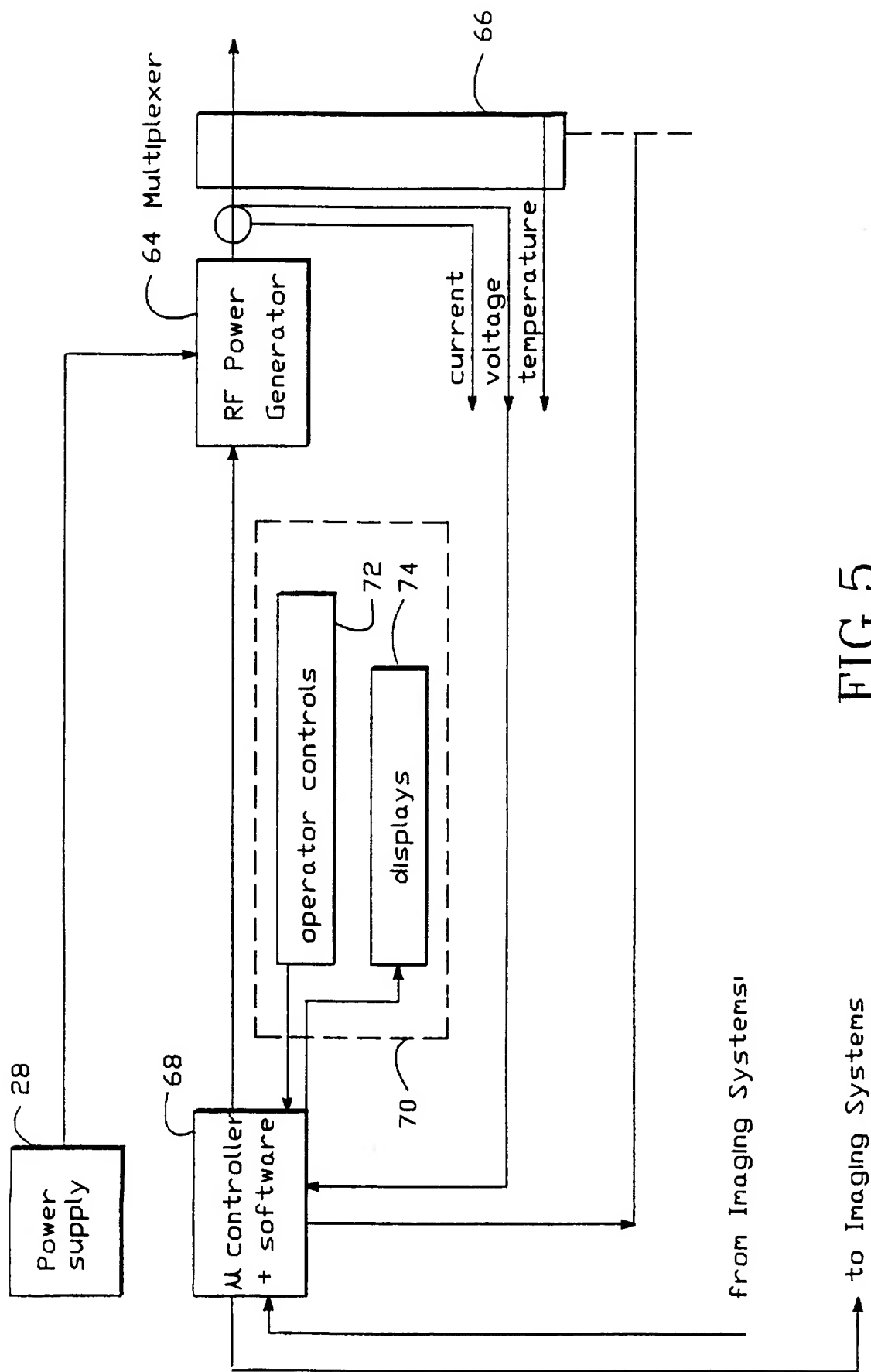


FIG. 5

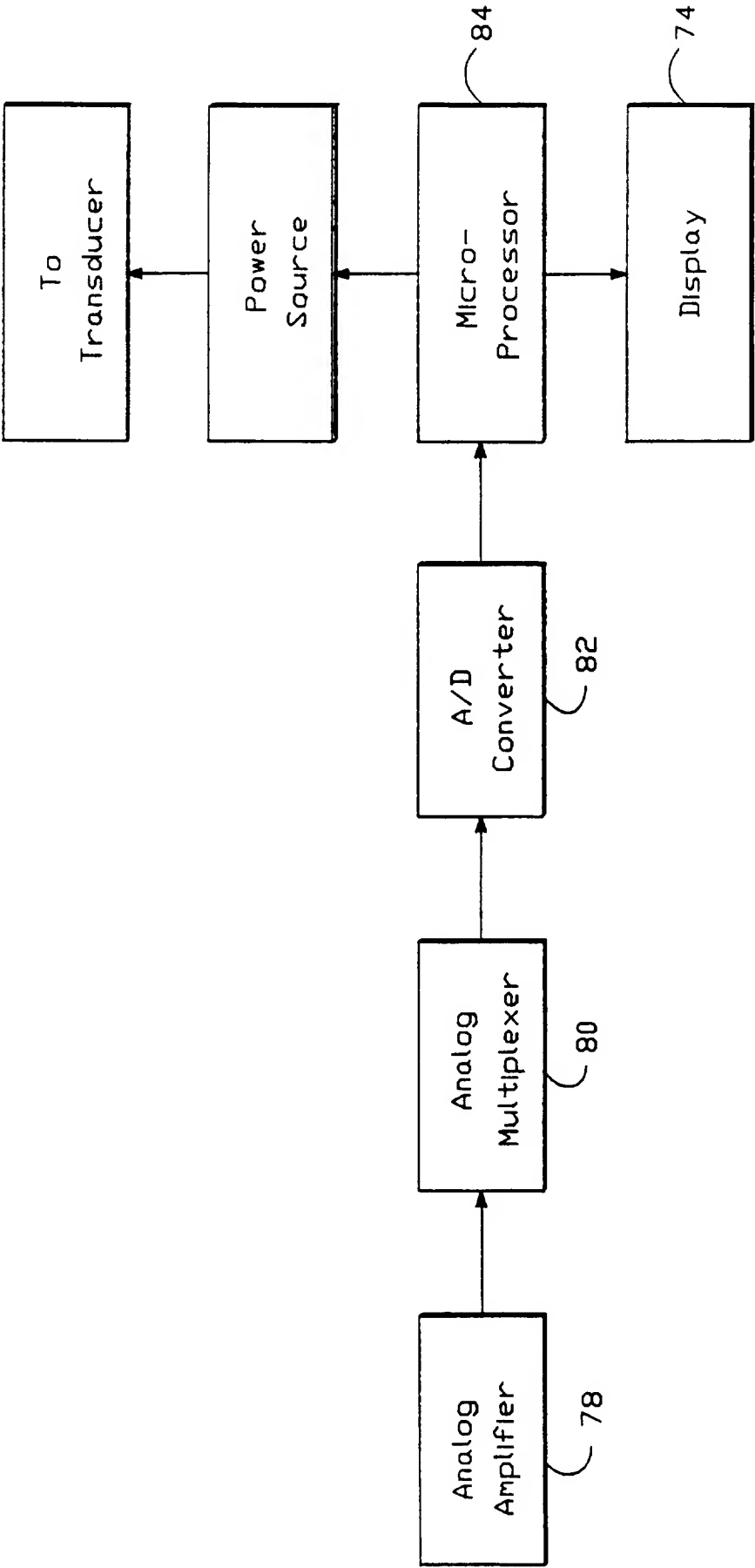


FIG.6

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/13608

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61N1/40 A61H7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61N A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 96 34568 A (KNOWLTON) 7 November 1996 cited in the application see the whole document ---	1, 5, 6
A, P	US 5 569 242 A (LAX) 29 October 1996 see abstract; figure 9 ---	1, 5, 6
A	US 5 304 169 A (SAND) 19 April 1994 see abstract ---	1, 5, 6
A	US 4 381 007 A (DOSS) 26 April 1983 see column 2, line 15 - line 18 see column 1, line 18 - line 35 ---	1, 5, 6
A	WO 91 16942 A (IDESKA) 14 November 1991 see abstract -----	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search

7 November 1997

Date of mailing of the international search report

17/11/1997

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Papone, F

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/13608

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